THERMOPLASTIC ELASTOMERS • STRUCTURAL • WEAR
CONDUCTIVE • COLOR • FLAME RETARDANT

Medical Grade Color

Anna Kreofsky
Color Engineer
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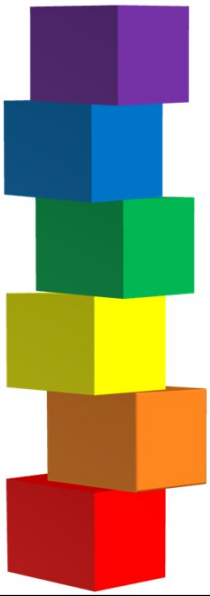
RTP Company Corporate Headquarters • 580 East Front Street • Winona, Minnesota 55987 USA
website: www.rtpcompany.com • email: rtp@rtpcompany.com • Wiman Corporation • +1 320-259-2554
TELEPHONE:
U.S.A. +1 507-454-6900 | SOUTH AMERICA +55 11 4193-8772 | MEXICO +52 81 8134-0403 | EUROPE +33 380-253-000 | SINGAPORE +65 6863-6580 | CHINA +86 512-6283-8383

ISO 9001 CERTIFIED

Today's Topics

YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

- Intro to RTP Color
- Biocompatibility
  - Statements
  - Color Packages
- Additive Masterbatch
  - Antimicrobial
  - Laser Marking
- Conclusion



Product Families

COMPREHENSIVE PRODUCT LINE

STRUCTURAL

WEAR RESISTANT

CONDUCTIVE

ELASTOMERS

FLAME RETARDANT

COLOR

FILM/SHEET

Compounds formulated to meet your needs

RTP Company Color Division

YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS

- 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

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

Color Specification & Tolerances

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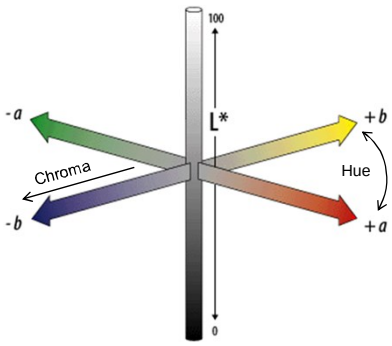
Numeric Color Modeling

- **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



$$DE = \sqrt{DL^{*2} + Da^{*2} + Db^{*2}}$$

CIE 1931 xy

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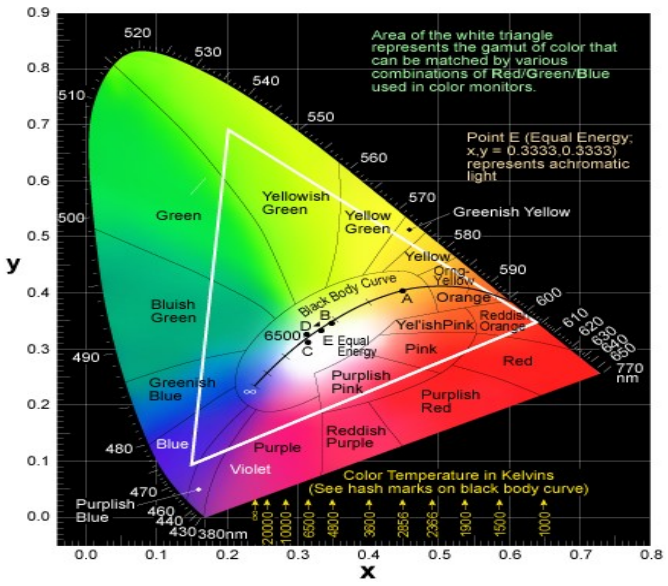

Color Evaluation & Control

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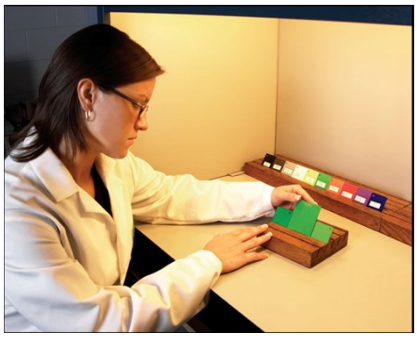

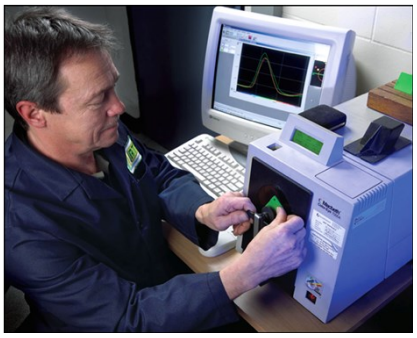

Visual Color Evaluation

- 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

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Part 10

Part 11

Part 5

Statement of Biocompatibility

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

This is to confirm that the pigments, resin(s), and additives(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 independent laboratory. The tested compounds have been found to meet I 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 differe mean score of the test extracts and the mean score of the corresponding co

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

Cytotoxicity Study Using the ISO Elution Method (IX MEM Extract), ISO

Plastic Formulation Selection

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Example of 18 Standard Colors that have passed ISO 10993-1 (custom colors available)

Unicolor™ - Universal carrier

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

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

Insight to RTP Color Number Nomenclature

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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

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

Laser Marking

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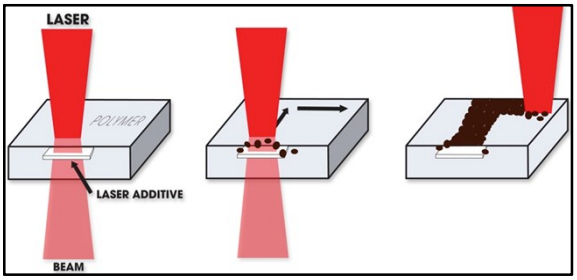
Basic mechanism

Laser energy absorbed causing a reaction

- Charring (dark mark)
- Foaming (light mark)
- Ablation (removal of layer, ex. Paint)



One Light – Two Marks

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Dark Marks

Light Marks

Laser Marking

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- 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

Source: iStockphoto LP

Advantages

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- 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

Laser Welding

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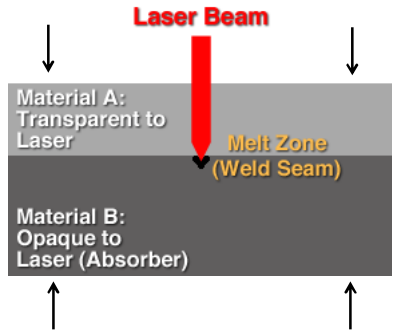
Laser Welding	→	Method for joining thermoplastic parts by using the thermal power of laser to bond materials



Laser Welding of Thermoplastics

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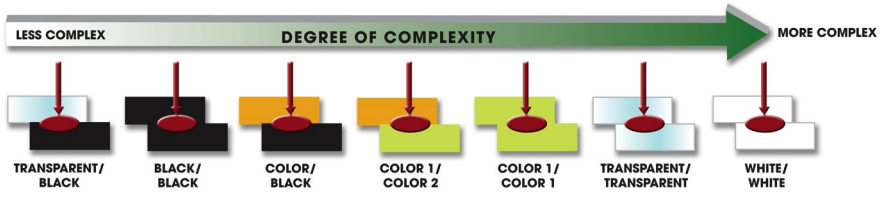
- The below chart indicates the degree of complexity for laser welding of various colors combinations
- RTP Company has experience with pigment/filler combinations, and loading levels, to support successful welding using both Diode and Nd:YAG lasers



Laser Welding of Thermoplastics

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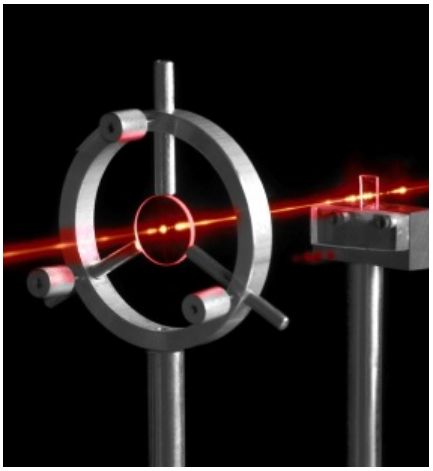
Advantages

- 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

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- 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

Thank You

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Any Questions?