COLOR • CONDUCTIVE • FILM/SHEET • FLAME RETARDANT
STRUCTURAL • THERMOPLASTIC ELASTOMERS • WEAR

Plastic Cures for Common Healthcare Hurdles

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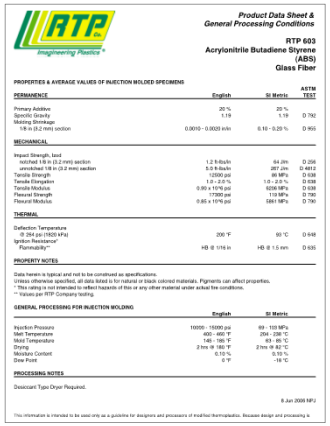
THE SITUATION

Customer asks for RTP 603 (ABS +20% GF)

Evaluate the situation from a non-Healthcare perspective

Evaluate the situation from a Healthcare perspective



Product Data Sheet & General Processing Conditions

RTP 603
Acrylonitrile Butadiene Styrene (ABS)
Glass Fiber

PROPERTIES & AVERAGE VALUES OF INJECTION MOLDED SPECIMENS

PERMANENCE	English	SI Metric	ASTM TEST
Primary Additive	20 %	20 %	
Specific Gravity	1.19	1.19	D 792
Molding Shrinkage			
1/8 in (3.2 mm) section	0.0010 - 0.0020 in/in	0.10 - 0.20 %	D 955
MECHANICAL			
Impact Strength, Izod			
notched 1/8 in (3.2 mm) section	1.2 ft-lb/in	64 J/m	D 256
unnotched 1/8 in (3.2 mm) section	5.0 ft-lb/in	267 J/m	D 4812
Tensile Strength	12500 psi	86 MPa	D 638
Tensile Elongation	1.0 - 2.0 %	1.0 - 2.0 %	D 638
Tensile Modulus	0.90 x 10^6 psi	6206 MPa	D 638
Flexural Strength	17300 psi	119 MPa	D 790
Flexural Modulus	0.85 x 10^6 psi	5861 MPa	D 790
THERMAL			
Deflection Temperature			
@ 264 psi (1820 kPa)	200 °F	93 °C	D 648
Ignition Resistance*			
Flammability**	HB @ 1/16 in	HB @ 1.5 mm	D 635

PROPERTY NOTES

Data herein is typical and not to be construed as specifications.
Unless otherwise specified, all data listed is for natural or black colored materials. Pigments can affect properties.
* This rating is not intended to reflect hazards of this or any other material under actual fire conditions.
** Values per RTP Company testing.

GENERAL PROCESSING FOR INJECTION MOLDING	English	SI Metric
Injection Pressure	10000 - 15000 psi	69 - 103 MPa
Melt Temperature	400 - 460 °F	204 - 238 °C
Mold Temperature	140 - 180 °F	63 - 85 °C
Drying	2 hrs @ 180 °F	2 hrs @ 82 °C
Moisture Content	0.10 %	0.10 %
Dew Point	0 °F	-18 °C

PROCESSING NOTES

Desiccant Type Dryer Required.

8 Jun 2006 MFJ

This information is intended to be used only as a guideline for designers and processors of modified thermoplastics. Because design and processing is

AGENDA

What's special about Healthcare?

- Care in material selection
- Care in formulation control

Hot technologies for Healthcare

- Common Hurdles
- TPE Compounds

WHAT'S SPECIAL?

What's so special about Healthcare applications?

⇨ Nothing!

WHAT'S SPECIAL?

What's so special about healthcare applications?

➡ Everything!

Unique requirements for medical devices

- May touch internal tissues or fluids!
- Changes can be bad!
- Not all suppliers support healthcare applications

BREAKING DOWN SPECIAL

May touch internal tissues or fluids!

Changes can be bad!

Not all suppliers support healthcare applications

Sterilization *Biocompatibility* *Change Control*

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STERILIZATION

Ethylene Oxide

Radiation

Autoclave (Steam)

STERILIZATION

Ethylene Oxide (EtO)

- Toxic gas
- Polymers require chemical resistance
- Most polymers OK for use with EtO

STERILIZATION

Radiation

- Gamma
- E-beam

Damages polymers via:

- Chain scission
- Crosslinking

Cumulative damage

STERILIZATION

Radiation resistant

ABS

Sulfones (PSUL, PES, PPSU)

PC
- Yellows with exposure
- Maintains properties

PE
- Crosslinks upon exposure

PP
- Requires stabilization

Not recommended

Polyacetal (POM)

PTFE

FEP

STERILIZATION

Autoclave (Steam)

- 120ºC to 135ºC with humidity exposure
- Exposure time from 3 to 15 minutes

STERILIZATION

Resistance to autoclave

Best
- PEEK
- PPSU

Good
- PP
- PA
- PSUL
- PC

Not recommended

Styrenics
- ABS
- Polystyrene

Polyesters
- PBT
- PET

Avoid materials with poor resistance to heat/humidity

BREAKING DOWN SPECIAL

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Sterilization | *Biocompatibility* | *Change Control*

BIOCOMPATIBILITY

Tissue/Fluid contact suitability often determined by biocompatibility

USP Class VI

ISO 10993

BIOCOMPATIBILITY

Most common ISO 10993 tests

Cytotoxicity

- Evaluate the toxic effects of the material on cells

Sensitization

- Determine skin or tissue reactions to prolonged exposure of material or extracts

Irritation

- Observe local irritation of skin, eye, or mucous membranes

QUESTIONS TO CONSIDER

What are some ways to ensure that a compound will pass part biocompatibility requirements?

Is this possible?

BIOCOMPATIBILITY OF INGREDIENTS

Specialty medical compounder material selection

Biocompatible resins

- Available in many different polymer systems

FDA compliant additives

- Most additives do not carry biocompatibility

CONFIDENCE IN FORMULATING

QUESTIONS TO CONSIDER

What other steps can be taken to ensure consistency in performance and long term safety and effectiveness?

BREAKING DOWN SPECIAL

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Sterilization *Biocompatibility* *Change Control*

CHANGE CONTROL

Formulation ingredients need to be locked

Required changes need to be communicated

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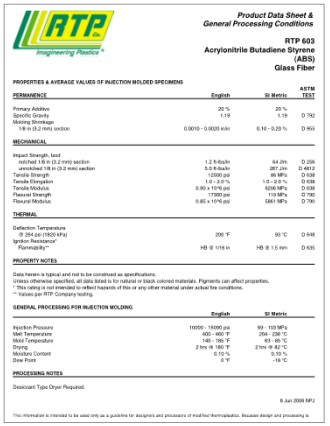

RTP Company
Engineering Plastics

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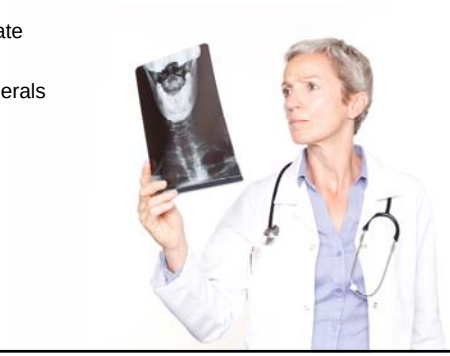
COMMON HEALTHCARE HURDLES

Radiopacity: visible using X-ray imaging

- Barium Sulfate
- Bismuth minerals
- Tungsten



COMMON HEALTHCARE HURDLES

Antistatic: For efficient drug delivery

- Reduce static build-up
- Dry powder drug delivery
- Clear and colors

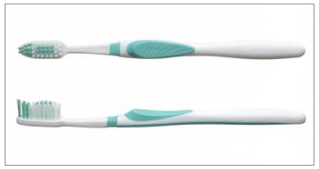
COMMON HEALTHCARE HURDLES

Reinforced Compounds:

for patient mobility

- Bed/chair components
- Wheelchair components
- Equipment bases

THERMOPLASTIC ELASTOMERS



THERMOPLASTIC ELASTOMERS

SBS • • TES • SEBS • • • •

Styrenic Elastomer Attributes

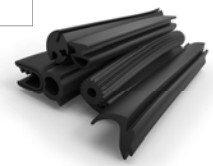
Highly Elastic
Highly Customizable
Design Flexibility
Broad Cost Spectrum
Great RT Compression Set

THERMOPLASTIC ELASTOMERS

• • • • TPV • • •

Vulcanize TPE Attributes

Broad temperature range
Improved chemical resistance
Easily colorable
Broad cost spectrum
Great room temp compression set



THERMOPLASTIC ELASTOMERS

• POE • • • • TPU • COPE • PEBA

POE, TPU, COPE, PEBA

Variety of performance

- Low cost to high temperature and performance

Base resins available as colors

Excellent starters for alloys

THERMOPLASTIC ELASTOMERS

SBS • POE • TES • SEBS • TPV • TPU • COPE • PEBA

• **Standard** – Compounds common to the market

• **TPE Alloys** – Combining neat technologies to optimize performance

• **Specialties** – Incorporating RTP additive expertise

STANDARD TPE MD GRADES

RTP 2700S MD Materials (Styrenic)

Gaskets & Stoppers	Certain Plunger Tips
Non-slip grips	PP Overmolds (soft touch)
Buttons & Locators	Skin Interface Areas
Supported Profiles	Dropper Bulbs

RTP 6003 MD & 6042 MD Materials (Bondable Alloy)

Polar Substrate Overmolds	Unique stand-alones
Electronic Housings	Adhesive elimination
Surgical Tool Handles	Medical Product Branding
“Rubber Armor”	Drug Delivery Device Grips

SPECIALTY ADDITIVE TPE MD GRADES

TPE + Specialty Additives: Design Attributes

Biocompatible Color	Conductivity
Radio Opacity/Gravity	Anti-Microbial
EMI Shielding	Flame Retardant
Friction Modified	Reinforcement

TPE SPECIALTIES – MEDICAL

TPE + Specialty Additives: Application Areas

Anti-Static / O_2 Environment	Color: Branding
Catheter Tips	Color: Identification
Strain reliefs	Sticktion elimination
Sensors/Diagnostics	High Stability/Stiffness

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