Mediprene® 500434M

Thermoplastic Elastomer

ELASTO

Message:

ELASTO have developed a range of Mediprene thermoplastic elastomers (TPE) for plunger seals in single-use syringes.
The TPE seal, which is mounted on the end of the plunger, needs to provide a leakproof seal with the syringe barrel. As ease of use for the medical practitioner and patient comfort are also key requirements, the seal helps to optimize plunger movement for accurate dosage control and ease of injection.
Regulatory compliance
Originating from medical raw materials with high biocompatibility status and compounded under clean conditions, Mediprene TPEs are the material of choice for medical customers who want to maximize the probability that their devices will pass relevant medical tests.
The raw materials in these compounds comply with food contact norms like FDA 21CFR and Commission Regulation (EU) No 10/2011. All polymers used have passed tests according to USP class VI and the paraffinic oil has passed the USP Mineral Oil NSF H1, reg 125038 and also the European Pharmacopeia, liquid paraffin.
Mediprene TPEs are latex free, which reduces the risk of allergic reactions. Representative grades have passed cytotoxicity tests according to ISO 10993-5 and biocompatibility tests according to USP Class VI.

General Information	
Features	Biocompatibility Compliance of Food Exposure
Uses	Medical/nursing supplies
Agency Ratings	FDA Food Exposure, Not Rated ISO 10993 Part 5 USP Class VI Europe 10/1/2011 12:00:00 AM
Appearance	Translucent
Processing Method	Extrusion Injection molding

Physical	Nominal Value	Unit	Test Method
Specific Gravity	0.880	g/cm³	ASTM D792
Melt Mass-Flow Rate (MFR) (190°C/2.16 kg)	0.60	g/10 min	ASTM D1238
Hardness	**Nominal Value**	**Unit**	**Test Method**
Durometer Hardness (Shore A, 4.00 mm)	43		ASTM D2240
Mechanical	**Nominal Value**	**Unit**	**Test Method**
Tensile Strength			ASTM D638
--	9.00	MPa	ASTM D638
100% strain	1.20	MPa	ASTM D638
300% strain	1.80	MPa	ASTM D638
Tensile Elongation (Break)	850	%	ASTM D638
Elastomers	**Nominal Value**	**Unit**	**Test Method**

Tear Strength	15000	kN/m	ASTM D624
Injection	**Nominal Value**	**Unit**	
Rear Temperature	180 - 220	°C	
Middle Temperature	180 - 220	°C	
Front Temperature	180 - 220	°C	
Mold Temperature	20 - 50	°C	
Extrusion	**Nominal Value**	**Unit**	
Cylinder Zone 1 Temp.	150 - 210	°C	
Cylinder Zone 2 Temp.	150 - 210	°C	
Cylinder Zone 3 Temp.	150 - 210	°C	
Cylinder Zone 4 Temp.	150 - 210	°C	
Cylinder Zone 5 Temp.	150 - 210	°C	

Recommended distributors for this material

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