

THERMOLAST® M TM9HET (Series: MC/HE)
KRAIBURG TPE - Thermoplastic Elastomer
General Information
Product Description

The MC/HE series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its elasticity and transparency at high hardness plus its adhesion to PP. The compounds are transparent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

Typical applications

- Squeeze bottles
- Luer lock
- Drip chamber
- Closure caps

Material advantages

- US DMF listed
- Adhesion to PP
- Elasticity
- Stiffness
- Sterilizable (autoclave 134°C, β -/y-radiation 2x35 kGy, EtO)
- Weldable (Ultrasonic)
- Free from animal ingredients
- KRAIBURG TPE Medical Service Package
- ISCC PLUS ready (mass balance approach)

Regulations / Approvals

- Regulation (EU) No 10/2011
- US FDA CFR 21 (raw material conformity)
- VDI 2017
- ISO 10993-4 (Hemolysis)
- ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous irritation)
- ISO 10993-11 (Acute systemic toxicity)
- USP <88> (Biological Reactivity, Class VI)

General

Material Status	• Commercial: Active		
Availability	• Africa & Middle East • Asia Pacific	• Europe • Latin America	• North America
Features	• Autoclave Sterilizable • Ethylene Oxide Sterilizable • Good Adhesion	• Good Elasticity • Good Stiffness • No Animal Derived Components	• Radiation Sterilizable • Ultrasonic Weldable
Uses	• Bottles	• Caps	• Medical/Healthcare Applications
Agency Ratings	• EU 10/2011 • FDA • ISO 10993-10	• ISO 10993-11 • ISO 10993-4 • ISO 10993-5	• USP 88 Class VI
Appearance	• Clear/Transparent		
Processing Method	• Injection Molding		

Properties ¹

Physical	Nominal Value	Unit	Test Method
Density	0.900	g/cm ³	ISO 1183
Elastomers	Nominal Value	Unit	Test Method
Tensile Stress ² (Yield)	2610	psi	ISO 37
Tensile Elongation ² (Break)	550	%	ISO 37



Tear Strength ³	571 lbf/in	ISO 34-1
Compression Set ⁴		ISO 815
73°F, 72 hr	52 %	
158°F, 24 hr	79 %	
Hardness	Nominal Value	Unit
Shore Hardness		Test Method
Shore A	97	ISO 48-4
Shore D	52	

Notes

¹ Typical properties: these are not to be construed as specifications.

² Type S2, 7.9 in/min

³ Method Bb, Angle (Nicked)

⁴ Method A

