KRAIBURG TPE

Datasheet

MC/HE Series

THERMOLAST® M

The MC/HE Series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by combining excellent elasticity with high hardness. The compounds are produced exclusively by a special medical unit and available in translucent colors.

Typical applications

- Drip chamber
- Luer lock
- Squeeze bottles

Material advantages

- Adhesion to PP
- DMF listed
- Free of animal based ingredients
- High elasticity
- High stiffness
- KRAIBURG TPE Medical service package (description below)
- Sterilizable (autoclave 134 °C, gammaradiation 2x35 kGy, EtO)
- Tested according to ISO 10993-5

Processing Method: Injection Molding

	Color / RAL DESIGN	Hardness DIN ISO 7619-1 ShoreD ShoreD	Density DIN EN ISO 1183-1 g/cm3	Tensile Strength [1] DIN 53504/ISO 37 MPa	Elongation at Break [1] DIN 53504/ISO 37 %	Tear Resistance ISO 34-1 Methode B (b)(Graves) N/mm	CS 72 h/23 °C DIN ISO 815-1 Method A %	CS 24 h/70 °C DIN ISO 815-1 Method A %	CS 24 h/100 °C DIN ISO 815-1 Method A %
TM9HET	transparent	39	0.900	18.5	750	73.5	62	83	85
TM0HET	transparent	52	0.900	17.0	550	98.5	42	95	98

[1] Deviating from ISO 37 standard test piece S2 is tested with a traverse speed of 200 mm/min.

All values published in this data sheet are rounded average values.

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THERMOLAST® M Medical-Service-Package

All medical compounds are tested according to ISO 10993-5 (Cytotoxicity) and listed under a Drug Master File.
Selected medical compounds are tested according to described medical basic approvals: USP Class VI (chapter 88), ISO 10993-4 (Haemolysis, indirect in human blood), ISO 10993-10 (Intracutaneous Irritation) and ISO 10993-11 (Acute Systemic Toxicity). No changes in formulation or process (except of necessary adjustments e.g. due to new regulations).
If any changes are necessary, KRAIBURG TPE will inform the customers at least 24 months in advance.
THERMOLAST® M Compounds are produced on a dedicated medical compounding line.

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Processing Guideline Injection Molding	
Cylinder temperature	180 - 200 - 220 °C, max. 250 °C (360 - 390 - 430 °F, max. 480 °F)
Hotrunner	Hot runner temperatures: 200 -250 °C (390 - 480 °F). The runner should be empty after a maximum of 2 - 3 shots.
Injection pressure	200 - 1000 bar (2900 - 14504 psi) (depending on the size and weight of the part).
Injection rate	In general, the fill time should not be more than 1–2 seconds.
Hold pressure	We recommend to derive the optimum hold pressure from determining the solidification point, starting with 40 % - 60 % of the required injection pressure.
Back pressure	20 - 100 bar; if color batches are used, higher back pressure is necessary.
Screw retraction	If an open nozzle is used processing with screw retraction is advisable.
Mold temperature	25 - 40 °C (77 - 104 °F)
Predrying	Pre drying of the material is not necessary; if surface moisture forms as a result of changes in temperature, the material should be dried for 2 - 4 hours at 60 - 80 °C (140 - 175 °F).
Needle valve	With materials < 50 Shore A the use of a needle valve is advisable.
Screw geometry	Standard 3-zone polyolefine screw.
Residence time	The residence time is to be set as short as possible with a maximum of 10 minutes.
Cleaning recommendation	For cleaning and purging of the machine it is appropriate to use polypropylene or polyethylene. Machine must be PVC-free.

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