

MC/RS Series

THERMOLAST® M

The MC/RS Series is your material solution for applications requiring basic medical approvals such as USP Class VI, USP 661 and ISO 10993-4, -5, -10, -11. The series is characterized by excellent resealing properties. The compounds are produced exclusively by a special medical unit and available in translucent colors.

Typical applications

- Closures
- Infusion stoppers
- Membranes

Material advantages

- Adhesion to PP
- DMF listed
- Excellent compression set
- For injection molding and extrusion
- Free of animal based ingredients
- KRAIBURG TPE Medical service package (description below)
- Outstanding resealing properties
- Sterilizable (autoclave 134 °C, gamma radiation 2x35 kGy, EtO)
- Tested according to USP Class VI, USP 661 and ISO 10993-4, -5, -10, -11

Processing Method: Extrusion, Injection Molding

	Color	Hardness Shore A DIN ISO 7619 ShoreA	Density DIN EN ISO 1183-1 g/cm ³	Tensile Strength ¹ DIN 53504/ISO 37 MPa	Elong. at Break S2 ¹ DIN 53504 / ISO 37 %	Tear Resistance DIN ISO 34-1 N/mm	Compr. Set 72h/RT DIN ISO 815 %	Compr. Set 24h/70°C DIN ISO 815 %	Compr. Set 24h/100°C DIN ISO 815 %
TM3RST	translucent	33	0.890	7.5	800	12.0	9	20	30
TM4RST	translucent	43	0.890	9.0	850	14.0	11	23	30

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

THERMOLAST® M Medical-Service-Package

THERMOLAST® M compounds are tested according to the medical base certifications USP class VI, USP 661, ISO 10993-4 hemolysis, indirect in human blood, ISO 10993-5 cytotoxicity, ISO 10993-10 intracutaneous irritation, ISO 10993-11 acute system toxicity, and listed as Drug Master File. No changes in formulation or process (except of necessary adjustments 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.

All values published in this data sheet are rounded average values.
Specification limits are based on three-fold standard deviation from the average value.

This datasheet is an extract of the KRAIBURG TPE program. Please contact KRAIBURG TPE to select the compound suitable for the requirements.

Disclaimer: The information provided in this documentation corresponds to our knowledge on the subject at the date of its publication and may be subject to revision as new knowledge and data becomes available. All values reported are typical values based on sample test results and are not a guarantee of performance. The responsibility to conduct testing to determine suitability of use for the particular process or end-use application remains with the customer. KRAIBURG TPE does not warrant or assume any liability with regards to the use of the information presented in this document.

Tests of the MC/RS Series

- USP class VI (chapter 88)
- USP 661 (in vitro)
- ISO 10993-4 hemolysis, indirect in human blood
- ISO 10993-5 cytotoxicity
- ISO 10993-10 intracutaneous irritation
- ISO 10993-11 acute system toxicity
- DMF Nr. 25603

TM3RST

- ISO 10993-10 intracutaneous irritation and sensitization

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Processing Guideline Extrusion

Cylinder temperature	140 - 150 - 160 °C; max. 210° C (285 - 300 - 320 °F; max. 410 °F).
Pre drying	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°C (140° F).
Screw geometry	Standard three-zone screw (e.g. polyolefin screw). The screw must be able to provide sufficient shearing.
L/D ratio	At least 25
Compression ratio	At least 3.5 : 1
Screens / breaker plate	A breaker plate and a screen pack are recommended in the extruder configuration in order to increase pressure. In minimum two screen packs of 100 mesh are recommended.
Die land	3 - 5 mm (0,12 - 0,16 in.)
Extruder Head	Ca. 180 °C (355 °F)
Die temperature	Ca. 150 - 180 °C (302 - 356 °F)
Calibration	Generally not necessary; support elements may be required when extruding THERMOLAST® compounds with high hardness or when coextruding with standard thermoplastics.

Processing Guideline Injection Molding

Cylinder temperature	220 - 200 - 180 °C max. 250 °C (428 - 392 - 356 °F, max. 482 °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.

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Processing Guideline Injection Molding

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 - 50 bar (285 - 710 psi); if colour 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)
Pre drying	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 shut-off	With materials < 50 Shore the use of a needle seal nozzle 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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