KRAIBURG TPE

Datasheet

MC/AD1 Series

THERMOLAST® M

The MC/AD1 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 adhesion properties to polar thermoplastics such as PC, ABS, PC/ABS. The compounds are produced exclusively by a special medical unit.

Typical applications

- Flexible Connections
- Membranes
- Seals
- Soft touch
- Valves

Material advantages

- DMF listed
- Excellent mechanical properties
- For injection molding
- Free of animal basedingredients
- KRAIBURG TPE Medical service package (description below)
- Sterilizable (autoclave134 °C, gammaradiation 2x35 kGy, EtO)
- Tested according to USP Class VI, USP 661 and ISO 10993-4, -5, -10, -11

Processing Method: Injection Molding

	Color	Hardness Shore A DIN ISO 7619 ShoreA	Density DIN EN ISO 1183-1 g/cm3	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	Adhesion Renault D41 1916 (ABS) [2] N/mm	Adhesion Renault D41 1916 (PC) [2] N/mm	Adhesion Renault D41 1916 (PETG) [2] N/mm
TM3ADT	natural	34	0.930	3.0	550	8.0	3.0	3.0	3.0
TM4ADT	natural	40	0.940	3.5	500	7.5	4.0	4.5	4.0
TM5ADT	translucent	50	0.950	5.5	600	9.5	9.0	11.0	7.5
TM6ADT	translucent	59	0.960	6.5	600	11.5	10.5	11.5	10.0
TM7ADT	natural	73	1.000	8.0	650	18.0	22.0	22.5	7.0

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

[2] The adhesion quality depends on mold design, product geometry and process parameters.

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.

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

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

Tests of the MC/AD1 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. 25604

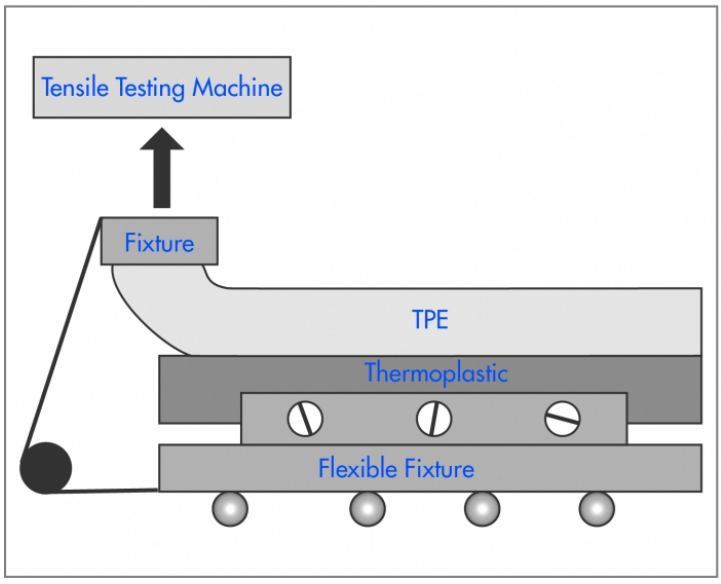
TM7ADT

- ISO 10993-10 intracutaneous irritation and sensitization

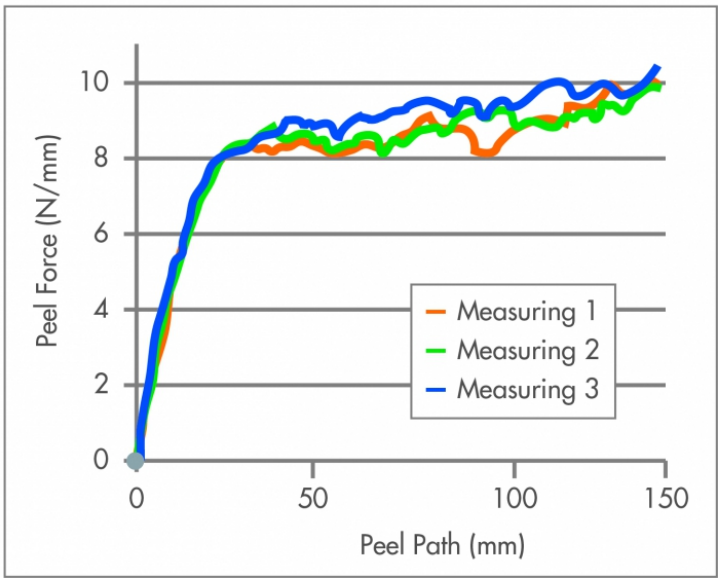
Description peel test

Peel test according to „Renault D41 1916“ standard

Test Setup



Example Diagramm as result of a peel test



The peel force is measured by
a tensile testing machine in N/mm , in relation to the peel path. Test piece dimensions: Thermoplastic part: 130 x 22 x 2 mm, TPE part: 130 x 20 x 2 mm.

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Processing Guideline Injection Molding	
Cylinder temperature	240 - 210 - 180 °C max. 250 °C (464 - 410 - 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.
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	The mold temperature depends on the hard component. A temperature exceeding 80 °C (175 °F) should be avoided. The common temperature is 40 - 60 °C (105 - 140° F).
Pre drying	To achieve optimum mechanical values, drying the material for 2 - 4 hours at 60 - 80 °C (140 - 175 °F) is recommended.
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.