



THERMOLAST® M – Medical Service Package

Highest Quality by KRAIBURG TPE

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1 About KRAIBURG TPE

KRAIBURG TPE is one of the world's leading manufacturers of Thermoplastic Elastomers (TPE) on the basis of hydrogenated styrenic block copolymers. In addition to custom-engineered solutions, the company also provides a broad range of market-specific formulations for diverse areas of application. For applications in the medical and pharmaceutical sectors KRAIBURG TPE develops medical-compliant TPE compounds. They are marketed under the brand name THERMOLAST® M.

2 Areas of Applications and Limitations of use

THERMOLAST® M from KRAIBURG TPE are specially developed compounds that can even be used for direct contact with bodily fluids or blood. For each application KRAIBURG TPE conducts a risk assessment based on MDR 2017/745. In this process, the applications are divided into four risk groups. Both the action time and the use of the article are assessed. Based on this assessment KRAIBURG TPE makes a decision on the potential use of THERMOLAST® M. In any case, only those applications are implemented that are in direct contact with blood for less than 30 days.

The THERMOLAST® M product line contains seven distinct material series, which each display a unique portfolio of special engineered characteristics. In general, the compounds of these series come pelletized, packed in bags of 20 kg, and are either transparent or translucent in color. However as KRAIBURG TPE offers services on coloration and color matching to individual color samples, all of these compounds can be obtained in any given color as well.

MC/tl Series:

TPE compounds of MC/tl series are specially designed for various applications in medical products. These applications range from sealings, e.g. for containers, soft touch elements, valves and membranes to mouthpieces for intubation.

Compounds of this series are available in different hardnesses, ranging from 30 through 90 Shore A.



MC/RS Series:

TPE compounds of MC/RS series are specially designed for highest demands on resealing capabilities at an optimum hardness range of 30 to 40 Shore A. These materials are commonly used in sealing and septum applications, for example those found in infusion bottles.



MC/LF Series:

TPE compounds of MC/LF series are specially designed for applications that require a low coefficient of friction to allow for improved smoothness of material running or easier piercing of material, e.g. syringe seals or septum applications. Compounds of this series are available in different hardnesses, ranging from 30 through 90 Shore A.



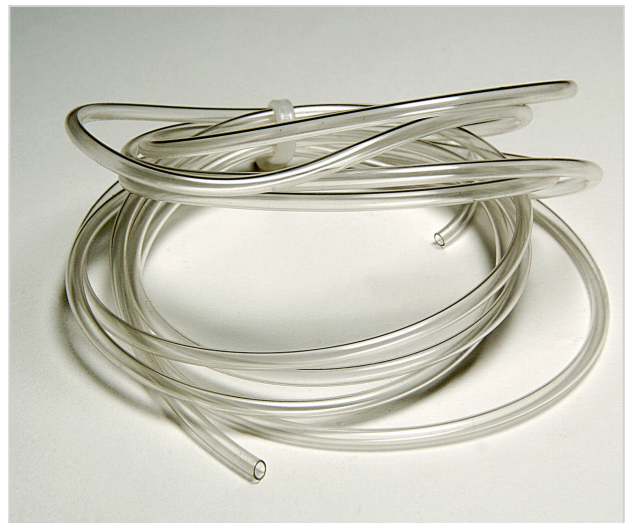
MC/AD1 Series:

TPE compounds of MC/AD1 series are specially designed materials for two-component injection molding with adhesion to polar thermoplastics. Superior peel forces are obtained on various thermoplastic materials, including PC, ABS, Copolyesters, and blends thereof. Compounds of this series are available in different hardnesses, ranging from 30 through 70 Shore A.



MC/HE Series:

TPE compounds of MC/HE series are specially designed materials for applications with highest demands on material elasticity and flexibility as well as transparency, e.g. tubings or connectors. Compounds of this series are available in 40 and 50 Shore D, respectively.



MC Series:

TPE compounds of the MC series are characterized by their adhesion to PP and PE and their good compression set. They are designed for applications such as pharmaceutical packaging, seals, valves and flexible connections. The materials are available in hardness ranges from 30 to 90 Shore A.



MC/AD/PA Series:

TPE compounds of MC/AD/PA series are specially designed materials for two-component injection molding with adhesion to various polyamides, such as PA6 and PA12. The compounds are available in hardnesses from 60 to 70 Shore A and can be used for grip applications, soft touch elements, seals, or flexible connections.



3 Listing and Modification

Compounds for the medical market are produced by KRAIBURG TPE in accordance with the principles of EU Regulation 2023/2006.

All medical compounds in the portfolio are tested according to ISO 10993-5 (Cytotoxicity). Selected medical compounds are tested according basic medical 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), ISO8871-1 (Part 1: Extractables in aqueous autoclavates)).

Necessary modifications and individual customer demands require close coordination between the customer and KRAIBURG TPE as well as detailed documentation. Additional medical tests and certifications must be conducted by the customer himself, if necessary.

4 Medical Service Package

KRAIBURG TPE offers a unique service package for its medical-compliant compounds. It includes the following services:

1. KRAIBURG TPE is obligated to maintain constancy of portfolio series materials (series MC/LF, MC/RS, MC/HE, MC/tl, MC/AD1, MC, MC/AD/PA) with respect to the formulations and manufacturing processes, by means of the Drug Master File. The only exception to this would be modifications made necessary by changes in legislature.
2. KRAIBURG TPE guarantees 24-month deliverability before modification of the formulation. This period starts upon issuing the respective Change Notification by KRAIBURG TPE.
3. KRAIBURG TPE requires its own suppliers to guarantee the purity of their raw materials.
4. KRAIBURG TPE guarantees for optimal production standards of THERMOLAST® M: Compounds for the medical and pharmaceutical sector are manufactured exclusively on separate production facilities allocated for these compounds.

KRAIBURG TPE offers its customers from the medical and pharmaceutical industry a comprehensive service package with maximum quality, safety and reliability. Nevertheless, KRAIBURG TPE provides no guarantee for the end applications specified by the customer.

Due to the numerous interconnected production steps, KRAIBURG TPE cannot provide any guarantee for the validity of the medical certifications of the compound for the end product. The customer himself is responsible for testing the end product for compliance with the required medical standards.

5 Release of Obligations

In the event of force majeure and hardships, KRAIBURG TPE GmbH & Co. KG, as well as all regional entities of KRAIBURG TPE GmbH & Co. KG, shall be temporarily released of all obligations.

Europe, Middle East, Africa

KRAIBURG TPE GmbH & Co. KG
Friedrich-Schmidt-Str. 2
84478 Waldkraiburg, Germany

Tel: +49 8638 9810 0
info@kraiburg-tpe.com

Asia Pacific

KRAIBURG TPE Technology (M) SDN.BHD.
Lot 1839 Jalan KP6
Kawasan Perindustrian Balakong
43300 Seri Kembangan, Selangor, Malaysia

Tel: +60 3 9545 6393
info-asia@kraiburg-tpe.com

Americas

KRAIBURG TPE Corporation
4365 Hamilton Mill Road
Buford, GA 30518, USA

Tel: +1 678 584-5020
info-america@kraiburg-tpe.com

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.



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