Mediprene® 500M

TPEs for medical applications,
standard series

HEXPOL TPE

CONTENTS

INTRODUCTION

Mediprene thermoplastic elastomers (TPEs) are suitable for a wide variety of uses in the medical and pharmaceutical market and new applications are being developed all the time. Mediprene compounds combine the performance of vulcanised rubbers with the processing properties of thermoplastics, delivering sophisticated design opportunities through a wide and flexible range of products.

Thermal and mechanical properties can be designed into the formulations and Mediprene compounds are fully recyclable and thus fulfil environmental requirements. Mediprene thermoplastic elastomers have proven to be strong alternatives as replacement for PVC. They are completely synthetic and latex free thereby minimizing allergy risks.

The right TPE formulation is the key to a safe and successful medical product. When a standard formulation does not meet the needs of a unique application, we will apply our expertise in formulating a custom solution. In this guide we show typical properties for our most common grades, these tables do not list all available properties and materials.

Please use this guide as an introduction to our Mediprene 500M standard series and contact us to discuss your specific requirements.

RAW MATERIAL SELECTION

In order to be called Mediprene, the raw material constituents of the compound must not only comply with food contact norms like FDA 21CFR and Commission Regulation (EU) No 10/2011 but also have medical approvals, assuring their biocompatibility. We have introduced a clear policy for the selection of raw materials for Mediprene compounds, typically consisting of; SEBS rubber, paraffinic oil and polypropylene:

- The rubber should be selected from a series of rubbers where representative grades have passed USP Class VI
- The paraffinic oil should be a medicinal white oil, complying with the European Pharmacopoeia for liquid paraffin and USP for mineral oils
- The polypropylene should be a medical grade that has passed USP Class VI

Originating from medical raw materials with high biocompatibility status and compounded under clean conditions, Mediprene TPEs are the material of choice for medical customers who want to maximize the probability that their devices will pass relevant medical tests.

REGULATORY COMPLIANCE

The basis for a successful outcome in medical tests is raw material selection, only allowing raw materials that, from a medical point of view, are highly qualified. The raw materials are then compounded together under clean conditions, with high consistency.

To further assure the customer, representative grades from the Mediprene standard series (500200M and 520580M, respectively) have been tested by NAMSA for cytotoxicity according to ISO 10993-5 and for biocompatibility according to ISO 10993-4 (Hemolysis), ISO 10993-10 (Intracutaneous Reactivity and Sensitization), ISO 10993-11 (Acute Systemic Toxicity) and USP Class VI. All materials that were tested successfully passed (copies of the certificates are available on request).

The other compounds in the Mediprene standard series with hardness values between 20 ShA (500200M) and 58 ShD (520580M) consist of the same raw materials and would therefore probably pass if tested. Note that there is an overlap between some tests in USP Class VI and tests described in parts of ISO 10993, meaning that the material is highly likely to pass parts of ISO 10993 when having passed USP Class VI. However, be aware that it is always the responsibility of the supplier of the finished product to perform relevant tests to ensure that the complete device fulfils the compliance criteria that have been set up for the product.

REGULATORY INFORMATION

The purpose of the next few pages is to briefly describe the tests in the United States Pharmacopoeia (USP) and ISO 10993 that have been done on representative grades from the Mediprene standard series. We also include comments on compliance with European Pharmacopoeia (EP) monographs.

CYTOTOXICITY TESTS – USP <87> AND ISO 10993-5

The elution test, as described both in monograph 87 of the United States Pharmacopoeia and in part 5 of ISO 10993, includes the following steps:

- The sample material is extracted with sodium chloride solution or serum-free mammalian cell culture medium under well-defined conditions
- A cell culture (L-929 mammalian fibroblast cells) is exposed to the sample extract as well as a positive and a negative control under well-defined conditions
- The cells are checked (appearance, cell lysis etc) after 48 hours and the response to the sample extract is judged with help of the guidelines in USP <87> as none, slight, mild, moderate or severe (grades 0-4).

The requirements of the test according to USP <87> are met if the response to the sample extract is not greater than 2 (mildly reactive).
ISO 10993-5 does not contain a pass/fail criterium for this test.

BIOCOMPATIBILITY TESTS ACCORDING TO USP (USP CLASS VI)

Biological reactivity tests, in vivo, are described in USP <88>. Six plastic classes are defined – USP Class I-VI, among which USP Class VI requires the most exhaustive testing. USP Class VI contains the following main tests:

- Systemic injection test
- Intracutaneous test
- Implantation test

Except for the implantation test, tests are carried out using extracts of the material to be tested. These extracts are prepared with differed solvents under well-specified conditions (surface area, temperature, time etc). For the implantation test small sample strips (minimum 10x1 mm) are used.

On the following pages is a brief description of each test and its purpose.

SYSTEMIC INJECTION TEST

PURPOSE : To determine the biological response of mice to the material by injection of specific extracts prepared from samples of the material.

TEST : Extracts of the sample material in sodium chloride solution, 1 in 20 solution of alcohol in sodium chloride solution, polyethylene glycol 400 and vegetable oil, respectively, as well as blanks are injected into albino mice. The mice are then observed at different time intervals up to 72 hours after injection. If none of the animals treated with the extract of the material shows a significantly greater biological reactivity than the animals treated with the blank, the material has passed the test.

INTRACUTANEOUS TEST

PURPOSE : To determine the local biological response of rabbits to the material by injection of specific extracts prepared from samples of the material.

TEST : Extracts of the sample material in sodium chloride solution, 1 in 20 solution of alcohol in sodium chloride solution, polyethylene glycol 400 and vegetable oil, respectively, as well as blanks are injected into albino rabbits intracutaneously. Each extract is injected into two animals on one side of the spinal column and the blank on the opposite side. The injection sites are examined for evidence of tissue reactions such as erythema, edema and necroses at different time intervals up to 72 hours after injection. The observations for both extract and blank sites are rated on a numerical scale based on guidelines given in USP <88> every time the sites are inspected. After 72 hours the overall mean score for each sample and each corresponding blank is calculated. If the difference in mean score between sample and blank is 1.0 or less the material extracted has passed the test.

IMPLANTATION TEST

PURPOSE : To evaluate the reaction of living tissue to the material by the implantation of a sample into the tissue of a rabbit.

TEST: The paravertebral muscle of two rabbits is implanted – each by four strips of the sample material and two strips of USP High-Density Polyethylene RS. The animals are kept minimum 120 hours and are then sacrificed by an overdose of anaesthetic agent or other suitable agent. The tissue is cut and the tissue portion surrounding each strip is examined for hemorrhage, necrosis, discolorations, infections and encapsulation. Encapsulation is determined by measuring the width of the capsule and rated on a numerical scale based on the guidelines given in USP <88>. The difference between the average scores for the sample and the control are calculated. If the difference is 1.0 or less the material has passed the test, alternatively if the difference in sample and control mean scores for more than one of the implant sites is less than or equal to 1 for any implanted animal.

Please note that, even though representative Mediprene grades have passed these implantation tests. We do not supply thermoplastic elastomers for implants.

EUROPEAN PHARMACOPOEIA (EP)

The European Pharmacopoeia contains monographs and other texts that are designed to be appropriate to the needs of regulatory authorities, people engaged in quality control and manufacturers of starting materials and medicinal products.

We have successfully tailor-made Mediprene grades that have passed selected monographs in chapter 3.1 of the European Pharmacopoeia, dealing with materials used for the manufacture of containers.

Please contact us for advice if compliance with a special EP monograph is needed.

FORMULATION STABILITY, CHANGE, NOTIFICATION AND AVAILABILITY

We are well aware of the severe consequences that most medical customers face when a formulation is changed. Therefore, Mediprene formulations are never changed unless one or more of its constituents cease to exist.

In case a formulation from the Mediprene standard series has to be changed due to a change or discontinuation of one or more raw materials, HEXPOL TPE will notify the customer. A volume of the unchanged compound corresponding to the quarterly updated two year forecast from the customer can then be made available to allow the customer to qualify a replacement compound.*

*With exception of Force Majeur situations.

CLEAN LINE PRODUCTION & QUALITY

Mediprene thermoplastic elastomers are produced with modern production equipment, designed for easy cleaning and with traceability and documentation based on the requirements of ISO 13485:2016 (medical devices). To achieve the high cleanliness that every medical customer has the right to expect, special measures are taken, such as:

- Thorough and well documented cleandown of the compounding line before running Mediprene compounds
- Closed systems from ribbon blender to packaging
- Special precautions in the ribbon blender and packaging areas
- Operators wearing clean clothes, gloves and hairnet

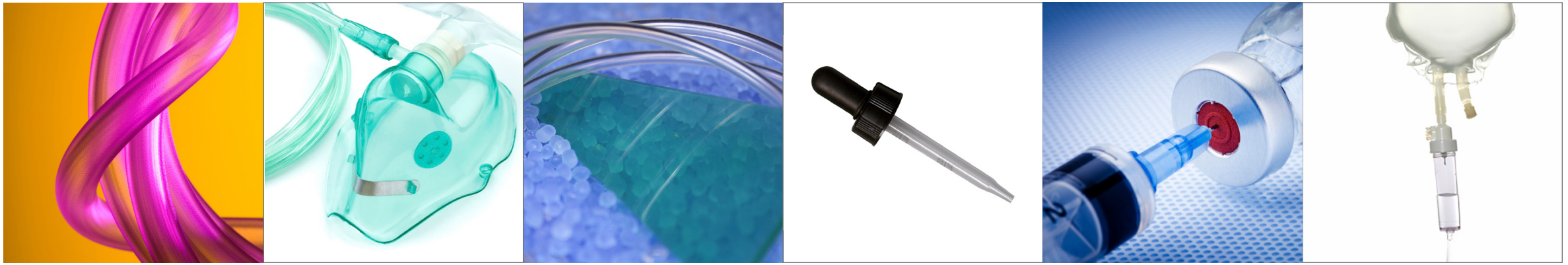
Mediprene grades are all manufactured under strict quality control, ensuring product property consistency. Our site producing Mediprene compounds is accredited to ISO 9001, ISO 14001 and ISO 13485.

KEY PROPERTIES

- Flexibility and elasticity
- Transparent grades available
- Can be easily coloured in any shade
- Soft touch
- Excellent resistance to many fluids used in the health-care environment
- PVC, silicone and latex free
- Adhesion to PP or PE without modification in overmoulding and coextrusion
- Processable with ordinary methods for thermoplastics processing, such as injection moulding and extrusion.
- Short cycle times

APPLICATION EXAMPLES

Mediprene thermoplastic elastomers can be used in various applications such as face masks, continence care products, connectors, IV systems, intubation equipment, seals, resealable membranes, drip chambers, wound care products, tubing, medical packaging and soft touch grips on medical devices. We are continuously working with our customers to develop new applications for Mediprene compounds.



STERILIZATION PERFORMANCE

Many medical devices are sterilized prior to use, sometimes several times during their lifetime. Therefore it is important that the materials used retain their properties after numerous sterilizations.

Representative Mediprene grades have been sterilized with the following methods:

- Steam/Autoclave
- Ethylene oxide (EtO)
- Gamma irradiation (25 kGy and 50 kGy)

Their properties have been evaluated before and after sterilization. This investigation shows that ethylene oxide sterilization is the most gentle sterilization method for Mediprene thermoplastic elastomers.

A sterilization guide is available to download from our website

A SELECTION OF MEDIPRENE 500M STANDARD SERIES GRADES

Material	Hardness [1] ASTM D2240 Shore A or D	Colour	Density ASTM D792 g/cm3	Tensile Strength ASTM D638 MPa	Stress at 100% Strain ASTM D638 MPa	Stress at 300% Strain ASTM D638 MPa	Elongation at Break ASTM D638 %	Tear Strength ASTM D624 N/mm	MFR ASTM D1238 g/10 min
500000M	0 A	Translucent	0.89	1	0.1	0.2	1000	5	100[5]
500050M	5 A	Translucent	0.89	2	0.1	0.2	1000	14	3[2]
500120M	12 A	Translucent	0.89	4	0.2	0.5	900	23	30[3]
500200M	20 A	Translucent	0.89	4	0.3	0.8	800	12	3[6]
500250M	25 A	Translucent	0.89	2	0.4	0.9	550	12	5[4]
500300M	30 A	Translucent	0.89	5	0.7	1.3	700	15	20[4]
500350M	35 A	Translucent	0.89	6	0.8	1.5	800	16	0.5[3]
500400M	40 A	Translucent	0.89	6	1.0	1.8	700	20	10[4]
500450M	45 A	Translucent	0.89	6	1.1	2.1	650	21	1[4]
500520M	52 A	Translucent	0.89	7	1.4	2.6	600	24	0.5[4]
500600M	60 A	Translucent	0.89	10	1.8	3.1	700	30	1.5[6]
500650M	65 A	Translucent	0.89	10	2.2	3.6	700	37	2.5[4]
500700M	70 A	Translucent	0.89	13	2.5	3.7	700	36	5[4]
500750M	75 A	Translucent	0.89	15	3.1	4.5	700	42	2[4]
500800M	80 A	Translucent	0.89	15	3.7	5.2	700	45	6[4]
500900M	90 A	Translucent	0.89	19	5.4	7.0	700	63	1[3]
520350M	35 D	Translucent	0.89	24	6.6	8.0	700	70	6[4]
520400M	40 D	Translucent	0.89	25	7.9	9.2	700	85	10[4]
520450M	45 D	Translucent	0.89	33	9.9	12	700	128	8[4]
520580M	58 D	Translucent	0.89	36	16	16	750	175	6[4]

[1] 4mm, after 15 seconds [2] 190°C/0.325kg [3] 190°C/2.16kg [4] 190°C/5kg [5] 150°C/2.16kg [6] 230°C/5kg

PROCESSING

Mediprene compounds can be processed using conventional thermoplastic equipment for injection moulding, extrusion etc. Processing temperatures normally range from 180°C to 210°C. The compounds in the standard series are not hygroscopic and thus do not need predrying.

SERVICE TEMPERATURE RANGE : From -50 to max +125°C (depending on hardness)

COLOURING RECOMMENDATIONS : For Mediprene compounds, polyolefin based masterbatch is recommended for colouring. Not to violate the high medical status of the Mediprene compound, the colour masterbatch should have passed USP Class VI or comparable tests.

WASTE DISPOSAL : All Mediprene grades are fully recyclable and, where possible, reprocessable during manufacturing. When burned, Mediprene compounds do not emit toxic fumes.

→ Further TPE processing & problem solving information is available to download from our website

WANT TO LEARN MORE?

Email the medical team at
mediprene@hexpolTPE.com

or visit www.mediprene.com

Other Mediprene Product Series →

Mediprene 500M : Plunger Seal Series

Mediprene 500M : Transparent Series

Mediprene Oil Free Series

Mediprene Sterilization Guide

Mediprene 2 Year Supply Guarantee

ABOUT HEXPOL TPE

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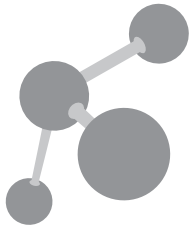
300+ EMPLOYEES WORLDWIDE

PRODUCTION PLANTS
Sweden, UK, Germany, China, USA

GLOBAL CAPACITY
> 80,000 tonnes p.a.

HEXPOL GROUP HEADQUARTERS
Malmö, Sweden



34,796+ PROPRIETARY FORMULATIONS

KEY MARKETS
Consumer, automotive, medical, construction, industrial

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