

PACKED WITH EXPERTISE



PROVAMED® — TPE-COMPOUNDS FOR PHARMACEUTICAL STOPPERS

THE CHANGE OF MATERIALS IN PHARMACEUTICAL STOPPERS

Pharmaceutical stoppers are used to seal injection and drug ampoules that are manufactured in extremely large numbers. For pharmaceutical packaging such as pharmaceutical stoppers, strict requirements and demands apply with regard to hygiene, safety, and function. Nowadays, rubbers are still often used as the basic material for manufacturing of such applications. The problem with these, however, are the NIAS (non-intentionally added substances). These are substances that are added unintentionally, and some of these can represent a hazard to health, putting patients and personnel at risk. A special production technique is also required for making stoppers out of rubber, one that only a few companies actually offer. This significantly constrains product availability. The production process with rubber also generates a lot of waste, which is contrary to the demand for greater sustainability and cost-effectiveness.

Against this background, the fact that butyl rubber is still the standard material used in some cases for the production of pharmaceutical stoppers is all the more astonishing. The industry has actually long since realigned its processes to favor a rubber-free material solution. With ProvaMed® TPE, a more sustainable and cost-effective alternative has already been created from TPE.

TPE INSTEAD OF RUBBER: AN ATTRACTIVE ALTERNATIVE

Thermoplastic elastomers (TPE) are soft-elastic plastics that can be processed using both injection molding and extrusion methods. As a separate class of materials, they sit between thermoplastics and elastomers. They combine the easy processing characteristics of thermoplastics, the elastic properties of rubber and the flexibility of elastomers.

TPEs are an ideal alternative to rubber, as their soft-elastic character makes them an excellent match for the requirements profile of pharmaceutical closures in that, above all, a secure and permanent seal is achieved.

Thermoplastic elastomers represent a family of polymers. The group of styrene block co-polymers (TPE-S) plays a fundamental role in this. Thanks to its advantageous properties, TPE-S has also established a strong profile in the medical technology sector. On this background, ACTEGA relies on TPE-S solutions that are free of plasticizers, BPA and phthalate-containing ingredients, and thus makes a valuable contribution to sustainability.

PROVAMED® – TPE FOR MEDICAL AND PHARMACEUTICAL APPLICATIONS

With the ProvaMed® brand, ACTEGA has developed a material especially for pharmaceutical and medical applications. ProvaMed® is a soft-elastic TPE that meets the most stringent requirements in terms of purity, hygiene, and safety.

The TPE ProvaMed® products that were developed especially for pharmaceutical stoppers

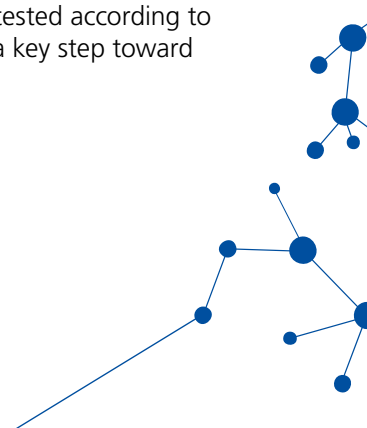
The following three products offer a safe and secure solution for the strict quality requirements of pharmaceutical stoppers:

- ProvaMed® TPE 6145 TL
- ProvaMed® TPE 6245 NC
- ProvaMed® TPE 6345 NC

The TPE compounds developed especially for pharmaceutical stoppers offer a significantly more attractive solution to the materials conventionally used, particularly with regard to processing, function and safety.

BENEFITS OF OUR PROVAMED® TPE FOR PHARMACEUTICAL STOPPERS

- Offers sustainable protection to patients and medical personnel. With ProvaMed® TPE as your pharmaceutical stopper material, you can achieve maximum cleanliness, hygiene, and reliability for your application.
- Since our ProvaMed® TPE plastic granules are permanently available and we can offer our customers delivery on demand, you can avoid bottlenecks in your material supply chain and therefore avoid downtimes in your plant.
- Our tested and verified ProvaMed® TPE plastics facilitate your work as a distributor of pharmaceutical stoppers and medical closures in regulatory qualification and compliance matters and reduce concerns around complying with the Medical Device Regulation by using non-cytotoxic TPE plastic granules that have already been successfully tested according to USP 381, enabling you to take a key step toward successful qualification.



PRODUCT CHARACTERISTICS

100 % REGULATORY COMPLIANCE

The products pass the physico-chemical tests prescribed in USP 381, as well as the ISO 10993-5 cytotoxicity test. The tests have been carried out by an external, independent testing laboratory and its testing certificates are available on request. In addition, the materials fulfill all regulatory functions according to USP 381, such as resealability after piercing with a cannula.

RESEALABILITY

The materials have excellent properties in relation to resealability. Even after being pieced multiple times with an 0.8-mm-diameter cannula, the materials maintain a complete seal.

FRAGMENTATION

With ProvaMed® TPE, standards-compliant results can be achieved with regard to fragmentation, guaranteeing protection for patients and safe handling.

PENETRABILITY

Pharmaceutical stoppers made from ProvaMed® TPE impress with safe handling and first-class user-friendliness, since they are easy to pierce with little force required.

STERILIZABILITY

Sterilizability was verified by observing the mechanical properties before and after each sterilization method (as per the table).

	PROVAMED® STERILIZABILITY PROCESS		
	PROVAMED® 6145 TL	PROVAMED® 6245 NC	PROVAMED® 6345 NC
Autoclave 121 °C	●	●	●
Autoclave 134 °C		●	●
Ethylene oxide (EtO)	●	●	●
Gamma radiation 25 kGy	●	●	●
Gamma radiation 50 kGy	●		●

PROFITABILITY

Using ProvaMed® TPE is considerably more profitable than the use of conventional materials. Unlike rubber, TPE can be recycled and reused. The general material costs and cycle times are lower and there is less waste.

	METHOD	PROVAMED®		
		6145 TL	6345 NC	6245 NC
Shore hardness A	ASTM D 2240, 5 s	45	43	45
Density	ISO 1183	0,87 g/cm ³	1,02 g/cm ³	1,21 g/cm ³
MFR (190 °C, 5 kg)	ISO 1133	31 g/10 min	3,5 g/10 min	
MFR (190 °C, 10 kg)	ISO 1133			5 g/10 min
Tensile strength*	ISO 53504	14,6 MPa	11,2 MPa	8,1 MPa
Tensile strength at 100 % elongation*	ISO 53504	0,9 MPa	1,4 MPa	1,8 MPa
Elongation at break*	ISO 53504	900%	890%	630%
Tear strength*	ISO 34-1	16 kN/m	22 kN/m	25 kN/m
Compression set (25 %, 23 °C, 22 h)	ISO 815	21%	17%	16%
Compression set (25 %, 70 °C, 22 h)	ISO 815	39%	33%	32%
Colour		translucent	natural	natural
Oxygen permeability	Pre Sens method	2,5 x 10 ⁻² [ppm/d]	1,8 x 10 ⁻² [ppm/d]	1,9 x 10 ⁻² [ppm/d]

*Standard specimen S2, 200 mm/min, cross to flow direction

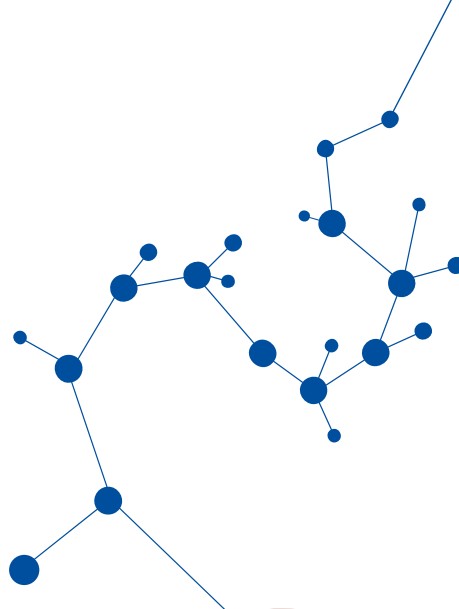


ACTEGA YOUR PROFESSIONAL PARTNER FOR WHEN EXPERTISE MATTERS

ACTEGA guarantees you a rapid and successful access to the market for your new products. Work with our experts in TPE. They will accompany you along the entire development process through to market launch. Thanks to seamless material supplies, your medical products are in safe hands. This gives you the security that you expect from us in this vital industry. Alongside material solutions for pharmaceutical vial closures, there are also PVC-free solutions for drip chambers, medical tubings, and syringes.

ABOUT ACTEGA

ACTEGA is a division of the internationally operational specialist chemical company ALTANA. With production facilities in Europe, South and North America and in China, ACTEGA develops, produces, and markets specialist paints, printing inks, adhesives, sealing putties and TPE compounds, focusing on strictly regulated markets such as the food and drinks industry. The "Specialty Consumer Goods" unit is part of ACTEGA and offers specialized TPE materials for sensitive applications. These include TPE plastic granules for applications involving food contact and TPE for the medical and pharmaceutical sector as well as the consumer goods industry. The expertise accrued over decades in the field of TPE compounding, especially in relation to low-migration, sophisticated TPE materials, played a key role in helping ACTEGA to become established as one of the world's leading manufacturers of soft-elastic plastics.



The information herein is based on our present knowledge and experience. The information merely describes the properties of our products but no guarantee of properties in the legal sense shall be implied. We recommend that you test our products in preliminary trials to determine their suitability for your intended purpose prior to use. No warranties of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. We reserve the right to make any changes according to technological progress or further developments. ACTEGA reserves the right to change or update the information without notice.