

ACTEGA – YOUR PARTNER WHEN IT COUNTS

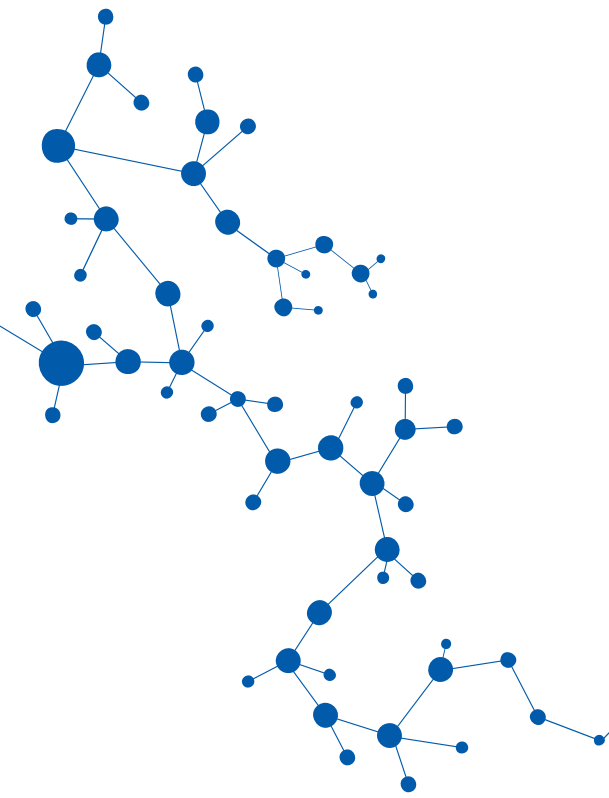
ACTEGA helps you to secure swift and successful market access for your new products. Collaborate with our TPE experts who will support you throughout the entire development process to market launch. Thanks to comprehensive provision of materials, your medical products are in good hands. This gives you the certainty you expect from us in this extremely important sector.



"Realize faster projects thanks to the confirmed quality of our TPE compounds and the very best support in all service areas."

Florian Schindler
Product Manager
New Business Development

Your contact:
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PACKED WITH EXPERTISE



PROVAMED® –
TPE-COMPOUNDS
FOR MEDICAL
DRIP CHAMBERS

THE NEW MATERIAL TREND IN THE MARKET FOR INFUSION SETS

Medical products such as drip chambers which are manufactured in large quantities must comply with stringent requirements. They should be safe, hygienic and economical in production as well as being as easy as possible to use. PVC has often been used in this area to date but this material – and the plasticizers associated with it - are increasingly subject to criticism. Among other things, it has been proven that certain plasticizers display properties which are toxic for reproduction and can interact with certain medications. With serious possible consequences: PVC plasticizers can be released, thereby putting both patients and personnel at risk. Certain active ingredients can also form deposits on the surface of the PVC material which impairs the effect of the respective drug.

There has long been a shift in people’s thinking in favor of PVC-free and therefore more sustainable solutions. The market for medical drip chambers is beginning to turn around.

TPE – THE PVC-FREE ALTERNATIVE

Thermoplastic elastomers (TPE) are soft-elastic plastics. Forming a material class of their own, they are positioned between thermoplastics and elastomers. They combine the easy processing properties of thermoplastics with the elasticity and flexibility of elastomers.

TPEs represent a very suitable alternative, especially for drip chambers, as their soft-elastic character eminently complies with the requirements profile of infusion sets in that a satisfactory compressive force profile is achieved. This makes it possible to obtain a well-balanced degree of material stiffness accompanied by good recoverability properties. Furthermore, TPEs are ideal for processing in injection-molding and extrusion processes, enabling the formation of drip chambers as well as infusion set tube components.

There are many types of thermoplastic elastomers. The group of styrene block copolymers (TPE-S) plays the most significant role in medical technology as they display a particularly high degree of flexibility. That is why ACTEGA relies on TPE-S solutions and consciously dispenses with any type of use of plasticizers or ingredients containing BPA or phthalates, thereby making a valuable contribution to the topic of sustainability.

PROVAMED® – TPE FOR THE MEDICAL APPLICATION

ACTEGA pools its TPEs for medical and pharmaceutical applications under the ProvaMed® brand. ProvaMed® stands for soft-elastic TPEs which comply with the highest requirements on purity, hygiene and safety. Accordingly, they are used for drip chambers, medical tubes, pharmaceutical plugs, or syringe piston seals.

Specially for applications ...

ProvaMed® TPE D1341 TP, ProvaMed® TPE D1345 TP and ProvaMed® TPE D1349 TP represent safe solutions for the high demands on performance and safety for medical drip chambers. They enable the realization of complex designs in elastic and ultra-transparent drip chambers.

PRODUCT FEATURES

HIGH TRANSPARENCY

Apart from absolute health safety, drip chambers also require outstanding transparency with a well-balanced degree of flexibility, rigidity and durability. Our ultra-transparent TPEs permit perfect optical control of the drip process as well as easy and swift adjustments to the fluid level.

STERILIZABILITY

Our TPEs for drip chambers can be sterilized using ethylene oxide (EtO) and gamma rays - without any negative impact on the material properties and without impairing the function of the adhesion sites, e.g. between the drip chamber and the tube. Sterilizability has been verified by an external, independent test laboratory.

BONDING ABILITY

Our TPEs offer an outstanding level of solvent bonding. Furthermore, ACTEGA avails of material solutions with a high precision fit between the tube and the drip chamber material. This has been tested in an extensive range of tests – in line with ISO 5836-4 – using solvents which are established in the sector, i.e. tetrahydrofuran (THF), methyl ethyl ketone (MEK), and cyclohexanone.

OTHER FEATURES

During the manufacturing process

- Optimized material flow for injection-molding
- Very good processing properties
- MFI and flow performance ensure attractive cycle times

During application

- Well-balanced degree of rigidity and recoverability
- Pleasant haptics

Product	PROVAMED® D1341 TP	PROVAMED® D1345 TP	PROVAMED® D1349 TP
Shore D	D-41	D-45	D-49
Density	0,98	0,98	0,98
Optics	high transparency	high transparency	high transparency
MFR 190° / 5 kg	21,6	23,5	13,7
E-module [MPa]	799	1120	1160
Tensile strenght [MPa]	13,1	14,9	13,9
Elongation at break [%]	289	304	266

100% REGULATORY CONFORMITY

- Compliance with regulatory requirements
- USP class VI, <88> biological reactivity tests, in vivo
- In accordance with USP VI, biological tests for plastics
- Testing TPEs in accordance with ISO 10993-5
- Production in line with GMP Directive (EC) 2023/2006

BENEFIT FROM THE ADVANTAGES OF OUR PROVAMED® TPES FOR DRIP CHAMBERS:

- Protect patients and medical personnel over the long term. Our TPE solutions free of plasticizers attribute your medical technology valuable functions while complying with maximum demands on cleanliness, hygiene and safety.
- ProvaMed® TPEs offer you more flexibility, freedom of design, and extra sustainability. Use conventional solvents to bond the components made from soft PVC with those made from TPE or use our TPE solutions for drip chambers and infusion lines to design infusion sets which are entirely free of PVC. By doing so, you can reduce the volume of harmful PVC containing plasticizers in your products while working significantly more efficiently thanks to shorter cycle times and less installation effort.
- Design the qualification process for your medical products in an efficient and smooth manner. Our products have already been tested in accordance with ISO 10993-5, achieving outstanding results, for stress-free and easier qualification of your medical product.

