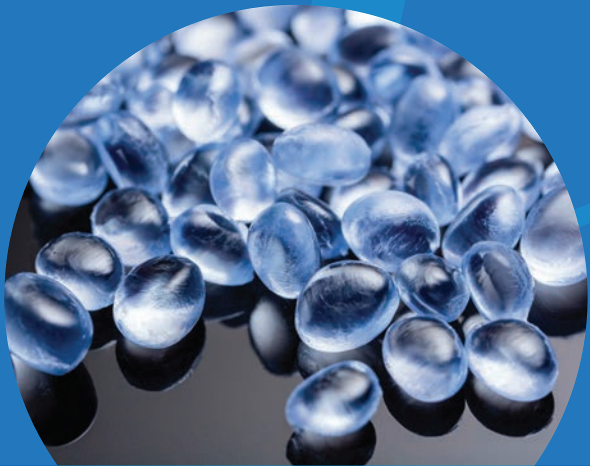

White Paper

Styrenic TPE Compounds:
Growth Drivers & Challenges in Medical Applications

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Over the past three decades, regulatory and market drivers, as well as cost pressures, have continued to generate a material choice discussion between polyvinyl chloride (PVC), thermoplastic elastomer (TPE) and rubber materials.

Many companies are trying to proactively address new regulatory dynamics, both in the United States and in many other global regions. Pressure is being applied by healthcare systems that are already implementing strategic initiatives for phthalate-free patient environments. TPEs are being viewed as a replacement for PVC in applications where phthalate- or plasticizer-free materials are desired. Globally, IV therapy producers are among the first in the medical device industry to transition from PVC to TPE materials.

TPEs also are replacing thermoset rubbers (such as silicone, polyisoprene and butyl rubber) used in elastomeric medical applications such as septum, stoppers and syringe plungers. The drivers for rubber replacement are improved processing, cost effectiveness and low extractables.

More recently TPEs also have been used to improved haptics, ergonomics, protection and/or function. TPEs are ideal for overmolding which provides a softer touch and improves ergonomics (such as grip) for a variety of surgical tools and devices. This can improve instrument control and fatigue reduction during long procedures for medical professionals.

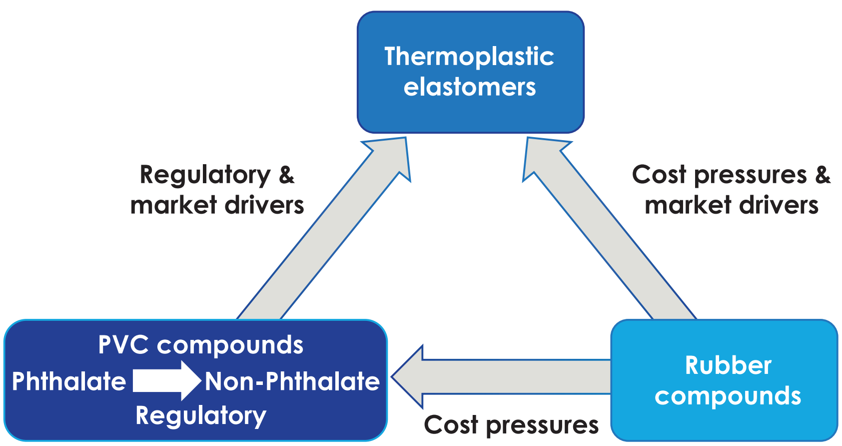

Figure 1: Summary of Trends Driving Material Choices

As a result of the above trends thermoplastic elastomer (TPE) usage has increased in both volume and commercial importance for medical devices and other related applications.

TPE compounds: basic definition

TPE compounds are a diverse family of rubber-like materials that offer properties typically associated with crosslinked or cured rubber, with the added advantage of thermoplastic melt processability.

Other common terminology used to describe thermoplastic elastomers are:

- thermoplastic rubbers
- thermoplastic vulcanisates (TPVs)
- thermoplastic polyolefins (TPOs)
- elastomer alloys

Thermoplastic elastomers of commercial importance can be classified into three groups and these are:

- styrenic block copolymers
- multiblock copolymers with crystalline hard segments
- hard polymer/ elastomer combinations

Styrenic block copolymers (SBS, SEBS, SEEPS) and multiblock copolymers (COPE/TPE-E, COPA/TPE-A & TPU, mPOE) are produced in polymerisation reactors.

Hard polymer/elastomer compounds (TPOs, TPE-S and TPVs) are produced using melt mixing compounders. In TPVs the elastomer phase is dynamically vulcanised during the melt compounding process.

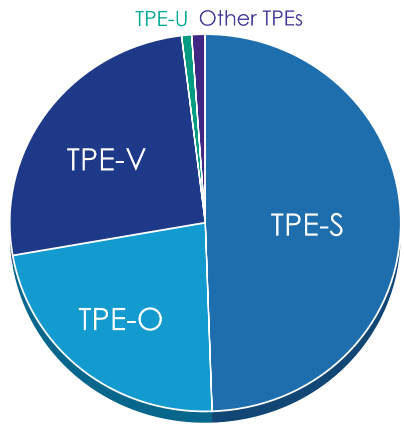

Figure 2: Estimated % market share of the different classes of TPEs in medical & hygiene applications*

Total global consumption of TPEs is expected to grow to 5,070,000 tonnes in 2018. Medical and hygiene applications is expected to account for 6.7% of total consumption (338,000 tonnes)*. Estimated % market share of the different classes of TPEs in medical and hygiene applications is shown in Figure 2. The styrenic TPE compound class (TPE-S) gives the most formulation and design flexibility, is most similar to PVC in that respect and accounts for almost 50% of the total consumption of TPEs in medical & hygiene applications.

* Source: Smithers Rapra market report The Future of Global Thermoplastic Elastomers

Styrenic TPE–S Compounds

Styrenic block copolymers, the base polymers in TPE-S, are uniquely versatile polymers and are in themselves a thermoplastic elastomer material but are not considered end products. Styrene block copolymers are based on simple molecular structures such as an S-E-S block copolymer, where S is a polystyrene segment and E is an elastomer segment and are differentiated by molecular weight, percentage styrene content (PSC) and the type and length of the elastomeric midblock. The most common styrenic block copolymers are those for which the elastomer segment is olefinic. Examples are shown in Table 1. Two basic polymerisation systems, anionic and cationic, are used to produce these styrenic copolymers.

Hard Segment - S	Elastomeric Segment - E	Formula
Polystyrene	Polybutadiene	S-B-S
	Polyisoprene	S-I-S
	Poly(ethylene-co-butylene)	S-E-B-S
	Poly(ethylene-co-propylene)	S-E-P-S
	Poly(ethylene-ethylene-co-propylene)	S-E-E-PS

Table 1: Common thermoplastic elastomers based on styrenic block copolymers.

The morphology of styrenic block copolymers can be best described by the domain theory. If the elastomer is the major constituent the block copolymers will have a morphology similar to that shown in Figure 3, where the polystyrene end segments form separate spheroidal regions, i.e., domains dispersed in a continuous phase.

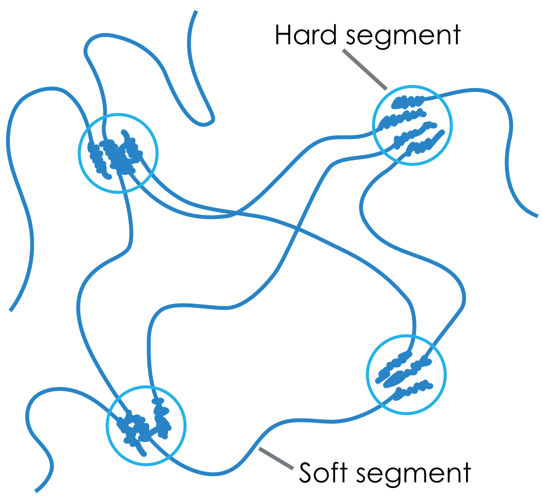

Figure 3: Morphology of styrenic block copolymers

At room temperature, these polystyrene domains are hard and act as physical crosslinks, tying the elastomeric mid-segments together in a 3-D network. In some ways this is similar to the network domains formed during vulcanisation of conventional rubbers using sulphur cross links. The difference is that these domains lose their strength when the material is heated. This allows the polymer to flow. When the material is cooled the domains harden and the networks regains its original integrity.

Functional TPE-S compounds are created by combining styrenic block copolymers with a number of selected additives (such as PP, PE, mineral oil, lubricants or antioxidants) during melt compounding. This is usually referred to as a TPE-S compound.

Specific formulations combined with the additive(s) of choice can deliver a wide range of properties and it is this versatility that enables TPE-S compounds to be used in numerous extruded and injection molded medical device components.

Originally marketed as a cost effective alternative to rubber in numerous applications, in more recent years, the development of styrene block copolymer chemistry, has led to improvements in compatibility and clarity with polypropylene, and the ability to formulate soft compounds without the use of mineral oils or plasticizing agents. This has enabled TPE-S compounds to target medical device applications where traditionally PVC compounds have been the material of choice.

Snapshot: drivers for conversion to TPE-S compounds

- **Economics:** ease of processing and cost effectiveness vs. thermosets
- **Low extractables:** absence of leachables and extractables (heavy metals), curing agents (used with thermoset rubbers), phthalate and plasticiser free (vs. PVC)
- **Regulatory:** plasticizer and phthalate free (vs PVC)
- **Allergy:** latex free (vs. rubber), no allergic reactions with long term TPE-S skin contact are known
- **Design:** TPE-S allows co-injection molding and design freedom

Snapshot: performance attributes of TPE-S compounds

- Broad durometer range in Shore A & D classifications
- Ideal for extrusion and injection molded products
- High-clarity grades for fluid monitoring applications
- Low density (0.88 - 0.99 g/cm3) for more parts/lb
- Low migration and drug absorption
- Halogen and phthalate free
- Representative grades are sterilizable by gamma, ETO or steam
- Kink resistance of specific grades comparable to PVC
- Can be readily bonded /adhered to a range of polymers
- Compression set of specific grades comparable to rubber
- Compatible with conventional extrusion and injection molding equipment
- Custom formulations can be engineered to meet critical application requirements

Challenges: TPE-S compounds in medical devices

Since there are pros and cons with every material choice, trade-offs also need to be considered for TPEs. Here are some considerations.

Solvent bonding. Using traditional manufacturing practices, TPE-S compounds would struggle to meet PVC's bonding capability. However, there are design modifications that can be made to circumvent the issue, including luer design, tubing dimension considerations and alternative adhesive solutions beyond solvent.

Kink resistance. Similar to solvent bonding, historically TPE-S compounds have struggled to match the kink resistance performance of PVC. However, in recent years, advancements in TPE-S formulation technology, TPE-S extrusion processing know how and tube design have closed the gap significantly.

Monolayer structure for IV therapy. Monolayer PVC provides the necessary performance attributes for IV bags. However, single layer TPE-S does not match the performance of PVC, therefore a TPE-S a multilayer structure is used in order to meet requirements.

Blood storage. PVC red blood cell bags provide much needed 42-day shelf life under refrigeration. Meeting this shelf life with a TPE-S blood bag is a huge challenge.

Pump performance. Matching the flex life characteristics (delivery accuracy over a 96 hour period across a broad range of environmental conditions) of silicone tubing is a challenge for TPE-S based pump tubing.

Resealability. In septum applications, self-sealing capacity ensures leak-free vials and eliminates concerns about sample contamination. Penetrability by medical needles or syringes, resistance to fragmentation and the ability to reseal after several punctures are all functional challenges for TPE-S compounds used in septum applications.

Cost vs PVC performance. Matching the cost vs performance of PVC compounds in disposable medical applications continues to be a significant challenge for TPE-S compounds.

Desired TPE-S compound supplier attributes

If you are a medical device OEM or a supplier subcontractor who has been entrusted with developing components for your client's new product, you may be uncertain as to how to evaluate a compounder with whom to partner. Selecting the right medical device compounder is critical not only to the commercial success of the product, but also to the commercialization timeline and related costs.

For tips on selecting the right supplier, refer to the checklist on the next page.

TPE-S compounds for traditional rubber and PVC applications

Rubber

- Baby nipples and teething rings
- Syringe plunger
- Closures & stoppers
- Incontinence condoms
- Resuscitation bags
- Pump tubing

PVC

- Film (IV bag)
- Tubing (catheters, respiratory, oxygen,
  IV infusion, pumps)
- Drip chambers
- Medical wire & cable

How to evaluate a compound supplier

- **Polymer neutral.** Does your supplier offer a broad range of products including PVC, rubber and emerging alternatives? Ideally, you also want to work with a compounder who is "polymer neutral." They don't have a vested interested in recommending one material over the other, but are driven by finding the right solution for your medical device application.
- **Experienced medical compounder.** What type of experience does the supplier have with medical compounds? Do they have a strong track record of successful medical company partnerships?
- **Medical market knowledge.** Are they abreast of device trends and usage environments? Are they up to date on the latest technologies so they can bring fresh ideas and robust solutions to your attention?
- **Functional performance.** Do they have the right experience to help guide you as you design your product? Can they suggest modifications that will help ergonomics or other performance attributes?
- **Global footprint.** With an increasing number of medical device companies marketing their products globally, manufacturing is oftentimes not confined to one region. In those instances, it is important to work with a compounder that also has a global footprint. Research to see if your compounder offers technical and sales support in other regions. Do they have access to raw materials in various parts of the world and can they replicate the grades?
- **Regulatory support**. Regulatory requirements for medical devices are becoming increasingly dynamic and more stringent around the world with different regulations at a continental, national and sometimes regional/state level. Therefore, it is critical that OEMs partner with compounders that have an in-house regulatory team that is not only cognizant of regulatory governing bodies, regional regulations, member state laws, test standards and quality management systems across the globe, but is also tracking potential proposed changes in the codes.
- **Subject matter experts/analytical support.** Polymers and polymer compounds play a central role in the manufacture and development of a wide range of medical devices. Understanding medical company needs, processes and applications, and translating these requirements into material properties, is critical to making the correct compounding recommendation. You want to partner with a technical team that has expert knowledge/experience to take you to the finish line.
- **Latest technology.** Before entering into a relationship with a medical compounder, it's important to understand their manufacturing capabilities. For example, do they have state-of-the art technology to pre- or post-dry materials? Can they premix materials? What does their direct material feed look like? Do they have "loss in weight" feeders that provide a high degree of accuracy when feeding polymers, injecting liquids or adding fillers and minor additives?