

TPVs for demanding food contact applications

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This article gives an overview of typical food contact regulations for plastics and rubbers, specifically thermoplastic vulcanisates (TPVs), primarily as they relate to the European and United States markets. Furthermore it explores various food contact applications that are typically made from TPV. The use of TPV is compared to other commonly used materials including thermoset rubber, PVC and styrenic block copolymers (SBCs, SEBS and SBS). We also show that TPV can be used in various innovative food sealing applications, and meet the criteria for regulatory requirements, physical properties, aesthetics, and durability that these applications require.

The designation "food contact materials" refers to materials and articles intended to come into contact with foodstuffs. The application scope includes but is not limited to packaging materials, cutlery, dishes, processing machines, and containers. The term also includes materials and articles which are in contact with water intended for human consumption. It should be noted however that this designation does not cover fixed public or private water supply equipment and materials or articles used for such equipment.

Sarlink TPV materials enable innovative solutions for seals and soft grips in demanding food contact applications. They show outstanding performance against specific requirements such as elasticity, increased temperature resistance and chemical resistance.

1. Food contact legislation

Materials used for food contact applications are held to high standards, and must meet formally defined requirements. Apart from consumer, functional and technical in-use requirements, food contact materials are also subject to various legislative and regulatory oversight. Food contact materials must be safe and must be produced under Good Manufacturing Practices. Additionally, under normal or foreseeable conditions these materials must not transfer any components into food that may:

- endanger human health,
- bring about an unacceptable change in the composition of the food,
- bring about deterioration in the organoleptic characteristics of the food.

A distinction has to be made between US legislation under the Federal Food, Drug and Cosmetic Act (FDA) and European legislation (European Framework Regulation). Although the principles underlying these regulations are the same in both the US and Europe, the approach to regulation is very different. It should be noted that these regulations are very distinct and not converging. The FDA is a stable regulation, while the food contact regulation in Europe is regularly being updated by way of amendments. Another notable difference is that the FDA requirements are exposure based, while the European regulations are based on a positive listing principle.

A region with an older food contact regulation is Japan. In order to prevent trade barriers, regions like Korea and China are in

the process of updating their old regulations with part of the Japanese, part of the European and part of the US regulations for food contact.

The legal entity that brings a food contact material to the market (producer or importer) must provide adequate information to the converter or manufacturer. Using this information as a qualifier, the converters must then perform their own assessment on the finished application or assembly. This assessment would include for instance any information about admixed additives or resins, production information, and other pertinent items.

Since legislation for food contact materials is complex and not globally harmonised, a dedicated assessment has to be performed not only for every new product to be launched, but also in every region where it is to be launched. Further adding to the complexity, regional regulations may differ as to how the application, part design, and conditions of use are taken into account.

Below, the regulatory requirements in the various regions will be explained.

1.1 US-Food and Drug Administration (FDA)

For all food additives an FDA clearance is required. The FDA definition of a food additive is very crucial:

- Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.

This implies that a raw material is not a food additive if it is not reasonably expected to become a component of food. For such raw material no FDA clearance is required. This principle is called the 'no migration principle'.

Food additives must be pre-cleared by the FDA, i. e. the subject of an applicable food additive regulation clearing the specific use, a Threshold of Regulation (ToR) letter granted in accordance with FDA's regulations. In

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case an additive is not covered by the existing FDA regulation, an applicable Food Contact Notification (FCN) can be requested. Unlike standard FDA regulations, FCNs are proprietary to the notifier and his customers. At this moment no ToR letters or FCNs exist for TPV materials.

Examples of FDA food additive regulations for TPVs are:

- 21 CFR177.2600 (rubbers articles intended for repeated use);
- 21 CFR177.1210 (closures with sealing gaskets for food containers);
- 175.300 (resinous and polymeric coatings);
- 175.105 (adhesives).

FDA allows self-determinations by companies that their products in a well defined application are not likely to become a component of food and thus are not subject to FDA's pre-clearance authority. It allows companies to bring products to market quickly, efficiently and safely. The application is said to be GRAS (generally recognised as safe).

Apart from the required FDA clearance it is mandatory that materials used for food contact applications are of suitable purity, and are produced under Good Manufacturing Practice (21 Code of Federal Regulations 174.5). This requirement is meant to guarantee the high quality of raw materials and articles, without any (cross) contamination during the production process.

1.2 Europe

In Europe, food contact materials and articles are regulated by the European Framework Regulation (EC) No 1935/2004. This legislation sets up the general requirements for all food contact materials. Since 1972, the EU Member States have been working on harmonising the various national regulations. The best developed harmonised regulation is the Plastics Directive. The Plastics Directive includes a positive exclusive list of monomers and since January 2010 the list of additives is positive exclusive as well. As of yet, substances such as solvents, pigments, polymer production aids and aids to polymerisation are not listed in any harmonised regulation.

Elastomers (TPV is an elastomer by definition in the food contact regulations) are explicitly excluded from the Plastics Directive. The national regulations for rubbers are not harmonised by the EU member states yet, and therefore they often vary between countries. For EU member states that do not have a regulation relating to rubber for food contact, the principle of mutual recognition can be used. In practice, this means that once a material or article is lawfully produced or marketed in one of the EU member states, other member states will also recognise the material or article as safe for sale.

The national regulations contain positive or incomplete lists of substances. These substances may be listed with a restriction in food, in most cases as a Specific Migration Limit (SML). If the migration of a substance with a SML at the intended use stays below the defined threshold, the application is deemed safe for use. The specific migration is calculated or tested at the condition of use. The conditions of use are amongst others the food species, the contact time and contact temperature. In some cases, food simulants can be used in place of actual food testing. Other relevant parameters of the application are the film or article thickness, and contact surface to volume of the contacted food ratio, amongst others.

In addition, the Overall Migration Limit (OML) of 60 mg/kg food is defined as a general measure of inertness. Europe adopted a GMP Regulation (2023/2006/EC), similar to the FDA.

1.3 Japan

Japan External Trade Organization's (JETRO) defined Specifications, Standards and Testing Methods for Foodstuffs, Implements, Containers and Packaging, Toys, Detergents (Jan. 2009). This legislation provides maximum limits for cadmium and lead, 2-mercaptoimidazole, and elution testing for phenol, formaldehyde, zinc, heavy metals, and evaporated residue.

1.4 China

China has three standards that are relevant for TPV food contact materials. They include

the hygiene standard for good manufacturing practice, the one for rubber articles and the additives standard GB9685. There is no hygiene standard for rubber materials and the standard for rubber articles is very old. Before 1 June 2010 there was the option to petition under the grandfather procedure for resins (such as TPV) and articles that are not clearly covered by an existing hygiene standard.

2. Food contact applications

Examples of food contact applications where elastic and soft-touch materials are fit for use are endless. Because of regulation, the distinction has to be made between single-use (for example caps & closures and corks) versus repeated use (for example food storage boxes). Some examples of applications lined up:

Repeated use:

- Food storage box seals
- Beverage container lids
- Grips for kitchen utensils such as knives, spatulas
- Bottle seals
- Buttons and seals for appliances
- Anti-slip layers on bowls, citrus pressers
- Flexible funnels
- Beverage dispensers
- Gaskets
- Seals and valves.

Single-use:

- Caps and closure liners
- Artificial corks.

2.1 Repeated use

As mentioned above, materials used for food contact applications have to meet high standards. It is important to note that this is not only due to regulatory requirements, but also to the functional and consumer requirements of the end product. Important properties for elastic materials in the food contact industry for repeated use can be classified as follows:

Sealability:

- Elasticity
- Cohesive bonding to PP
- Broad temperature range

Dishwasher resistance:

- Low deformation at increased temperatures
- Retention of properties after temperature cycles
- Excellent chemical resistance.

Appearance:

- Easy to colour
- Excellent part appearance and surface finish
- Soft touch and good grip
- Clean, non fatty, dry look and feel
- Design flexibility.

Product safety:

- Experience with regulatory compliance
- Risk assessment capabilities
- Partner in development
- Food and beverage contact.

Durability:

- High-end producers provide guarantees ranging from 30 years to lifetime.

TPVs are often selected for these types of applications because of their extremely good sealing and temperature (dishwasher) performance. The following outlines these functional characteristics in detail.

2.1.1 Sealability

Important in food contact material is that it should not transfer under normal or foreseeable conditions of use its components into the food in unacceptable quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics of the food. Using food storage containers as an example, this means that the box should not leak under any circumstances and the food inside should be preserved for an acceptable amount of time. In other words; the food contact material must act as a barrier between the enclosed food storage space and the outside world.

Design is a critical aspect of creating the proper seal, but sealing material selection can be just as important. The elastic resiliency, or resistance to compression set, of a material is the key factor in sealing performance.

For many food contact applications, this resistance to compression set must be maintained not only at room temperature, but also at environmental extremes ranging from the deep freezer all the way to the dishwasher. These types of extremes can lead to deformation and weakening issue for some TPE materials. In order to achieve the best elastic performance over this broad temperature range, TPVs have proven to be the best performing thermoplastic elastomers in such applications.

TPVs also provide an added benefit, as they are compatible with PP and PE materials, of which most modern food savers, bowls, and other plastic kitchen utensils are made. This compatibility allows TPVs to have a melt or cohesive bond with the substrate resulting in a strong and watertight interface between the hard and the soft parts of the application. Due to the polyolefin makeup of TPV, this can be achieved on a single piece of equipment using a two-shot injection moulding process.

2.1.2 Dishwasher resistance

For repeated use food contact applications such as seals, anti-slip and soft-touch layers, and grips on kitchen utensils it is important to know how the end-user treats the material. In addition to the stringent food regulation and tests in the microwave with all kinds of substrates such as oil, acids and water, there are also challenges that products face in the dishwasher.

All utensils' raw materials must withstand the conditions in the dishwasher, meaning no deformation caused by high temperatures and no degradation of material caused by chemical detergents. Although chemical resistance does not show a clear trend towards stricter requirements, temperature resistance requirements are increasing. Dishwashers' maximum temperatures have risen to 70 °C, and many high-end manufacturers have already extended their testing requirements to 85 °C. TPVs are to date the only thermoplastic elastomers that have passed these tests.

2.1.3 Appearance

Another critical area where TPVs consistently outperform other thermoplastic elastomer materials is appearance. While regula-

tory and technical requirements must be met in order to take a product to market, consumer tastes and expectations are often what dictate the commercial success of an application. While a water-tight seal may be the only technical requirement of an application, consumers often identify soft-touch, dry-feel, and overall aesthetics as secondary features indicative of high quality. Furthermore, colourability and surface quality are important as batch-to-batch appearance must be perfectly consistent once supplied to the stores. TPVs have proven to be a unique solution to this as they display both the physical and appearance properties that consumers demand.

2.1.4 Product safety

Due to the complex and regionally different structure of food contact regulation, cooperation between the raw material supplier and end part producer is incredibly important. Within the regulatory framework, it is often key to understand the type of food used (dry food vs. fatty food), the contact surface with the food and the types of migration tests with acids, olive oil, vinegar and water. Sarlink is committed to working very closely with its partners to provide all necessary regulatory support, and have the resources and expertise to issue food declarations on the materials used for specific food applications.

2.1.5 Durability

High-end producers in the field of food contact products have built both their reputations and bottom lines on the durability of their high-end household and kitchen articles. In many cases, 30 year or even life-time guarantees are offered, fostering an image of high quality that equates to strong customer loyalty. In order to maintain this reputation, the elastomeric materials used must exhibit colour stability, maintain elastic sealing properties, and adhere to the other materials used in the application – forever. Sarlink TPVs have an established track record of performance and durability that supports these requirements.

2.2 Proven success in demanding applications

Examples of repeated use food contact applications where Sarlink TPVs have been

successfully applied can be found in several products of Curver; producer of kitchen utensils famous for its long-standing image of high-end home and kitchen articles with an extended product quality guarantee. Curver has chosen Sarlink as their key supplier for the base material of their food container lid seals, for example in their so called 'Grand Chef' line (**fig. 1**). Sarlink TPVs are also being used for the soft-touch seals on their 'Pet Life' products (**fig. 2**). Next to dishwasher resistance and great sealability, also colourability are important characteristics of Sarlink TPVs that have led to Curver's choice for Sarlink TPVs.

2.3 Single use

Sarlink TPVs can also fulfill important needs in single use food applications. A good example of a single use application are synthetic wine corks (**fig. 3**).

The development of synthetic wine corks originated from an increased demand for wine corks combined with a shortage of natural cork trees. Since it takes a long time to grow and harvest cork trees, alternative solutions had to be found. Sarlink was instrumental in developing a specialised material to help bring synthetic corks into the mainstream. Although originally designed to solve a supply problem, many years of research suggest that synthetic wine corks actually do much more. The developed products secure the quality of the wine and result in a higher consistency from bottle to bottle. Bottles that traditionally would have spoiled because of 'corkage' became history due to the development of synthetic cork technology.

Wine corks require much more than good organoleptic properties. Watertight sealing, low wine aroma permeability, and controlled oxygen are important technical requirements that not only ensure the quality of the end product, but also can protect what many connoisseurs consider an investment.

Outside of the technical benefits, wine corks are also about the experience and nostalgic emotions of the wine drinker. Therefore it is critical that the materials being

used for the outer layer of the corks can be easily coloured, can be printed with the logo of the wine house, and resemble the appearance and performance of natural wine corks as closely as possible. Most importantly, the synthetic cork should not influence the smell and taste of the wine. Through very close cooperation in a joint development program over multiple years with Nomacorc, Sarlink's dedicated research and development resulted in high quality TPV products that meet all of these demands. Sarlink is currently the only producer of smell-free TPVs.

For single use applications like caps and closures, resistance to steam sterilisation and performance in hot fill processes can be important qualifiers.

3. Performance for food contact applications

3.1 Materials

Table 1 shows an overview of the relevant properties of soft materials currently being used in food contact applications. It is clear that every material has its own advantages and disadvantages and that, depending on

the final part design and requirements, different materials might have a good fit for use.

Both TPVs and SBCs are used in various elastic food contact applications.

TPVs:

- PP matrix with highly crosslinked EPDM particles (finely dispersed)
- strong chemical bonds in dispersed EPDM rubber phase
- thermoplastic processing like injection moulding, extrusion and blow moulding.

Blends of SBCs:

- PP with SEBS or SBS
- physical bonds in elastic SEBS or SBS rubber phase
- thermoplastic processing like injection moulding, extrusion and blow moulding.

The next several paragraphs will provide some test data and make a comparison between some commercially used SBCs and Sarlink TPVs in the food contact industry. Although both product families superficially seem to have similar properties, it will be demonstrated below that TPVs offer substantial advantages.

Fig. 1: Curver Grand Chef line



Fig. 2: Curver Pet Life line



3.2 Comparison of TPVs versus SBCs

As well as exhibiting a much lower density, Sarlink TPVs clearly outperform the current generation of SBCs when it comes to the following requirements:

- elastic performance at increased temperatures
- stable properties over a broad temperature range

- service temperatures and sterilisation above 100 °C
- long term resistance against dishwasher detergents
- resistance to food and beverage media.

Due to increasing demands for high temperature performance (e. g. steam sterilisation, hot fill, dishwasher) and chemical resistance (e. g. food ingredients, dishwash-

er detergents), TPVs are fast becoming the preferred material of choice for sealing and grips in food contact applications.

In the following paragraphs we will focus on the performance of Sarlink TPVs and SBCs at different temperatures, as increased temperature requirements are one of the main trends observed in the aqueous food contact (non fatty) market for soft plastic materials.

Fig. 3: Wine corks made of TPV

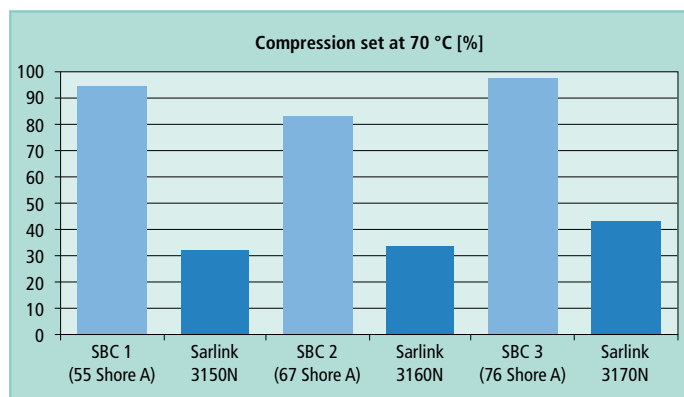


Fig. 4: Compression set of commercially used soft food contact materials

3.2.1 Compression set

A key performance criteria for plastic parts is that the geometry will not change when exposed to the temperatures and chemicals in the dishwasher. This becomes even more critical when the part is in direct contact with other articles and faces slight pressure with resulting distortion. The plastic part should not remain deformed when the pressure is released. Any failure of the part to return to form can result in severe marks and could influence the functionality of the application (e. g. sealing capacity).

Until recently, dishwashers had upper service temperatures of 70 °C, allowing part producers to test their products at 70 °C to 80 °C in continuous cycles. The new generation of dishwashers have maximum operation temperatures of 75 °C in order to get cleaner dishes without the addition of more aggressive detergents. Based on this trend, one of the major kitchen utensil producers in Europe recently changed its dishwasher testing to 125 continuous cycles at 85 °C.

A compression set test gives a good indication of the behaviour of plastic when it is deformed at elevated temperatures. **Figure 4** shows the compression set at 70 °C for some commercially available TPVs and SBCs currently being used in the food contact industry. The TPVs and corresponding SBCs have the same hardness to make a fair comparison.

A compression set of 100 % means that the material will not return to its original state at all after being compressed for a specified time at 70 °C. A compression set of 0 % means that the material will fully return to its original shape; a low compression set is desirable.

Tab. 1: Soft materials currently used in food contact applications

	Hard	Soft plastics				
	PP	PVC	Rubber	Sarlink	SBC	TPO
Weight per part	+	-	-	+	-	+
Soft touch	--	+/-	+	++	++	-
Bonding to PP and PE	++	-	+/-	++	++	++
Bonding to PA and ABS	--	+/-	-	-	+	-
Temperature range	+	+/-	++	+	+/-	+/-
Design flexibility	++	+	+/-	++	++	++
High temperatures	+	-	++	+	-	+/-
Sealing performance	--	+/-	++	+	+/-	-
Steam sterilisation	++	-	++	+	-	+
Hot fill applications	+	+/-	+	+	-	-
Detergent resistance	++	+/-	+	+	+/-	+
Dishwasher resistance	++	+/-	+	++	+/-	+/-
Oil resistance	++	+	+	+	-	+
Heat ageing	+	-	+	+	+/-	+
Durability	+	-	+	+	+/-	+
Toxicity	+	-	-	+	+	+

TPVs are clearly outperforming SBCs when it comes to compression set. In all cases the SBCs come close to 100 % deformation. The poor performance of the SBCs finds its main origin in the low glass transition point of polystyrene which is the physical crosslink in the SBCs. These crosslinks start weakening at relatively low temperatures around 70 °C, and find its peak around 90 °C.

The effect will be even stronger if the compression set test would have been performed at 85 °C (new dishwasher test standard). TPVs show less influence of the temperature on the compression set values. TPVs tested at 125 °C show compression set values for Sarlink 3150N, Sarlink 3160N and Sarlink 3170N of 52 %, 55 % and 63 % respectively, which at this elevated temperature is still a marked improvement over the SBCs tested at 70 °C.

Due to their relatively low temperature resistance, SBCs can't be used for typical hot fill applications and applications where steam sterilisation is applied. Furthermore, with the new standards for consumer dishwashers, the current generation of commercial SBCs will have difficulties passing the more severe test procedures and more stringent specifications set by the dishwasher manufacturers. Sarlink TPV based solutions will meet all these demands.

3.2.2 Modulus as a function of temperature

To get a better idea of the performance over a broad temperature range we also performed some Dynamic Mechanical Analysis (DMA) on the different materials. It is another way to show the difference between the chemical crosslinks in TPVs with the physical crosslinks in SBCs. In practical terms, this provides an indication on how the flexibility of the product varies with the temperature. **Figure 5** shows the E' modulus for the different SBCs as a function of

temperature. Sarlink 3170N was taken as a reference.

Both the Sarlink TPV and SBC 2 show a relatively stable E' modulus from -30 °C up to 160 °C. Both the SBC 1 and SBC 2 starts to weaken above 70 °C, but still has some residual stiffness up to 150 °C. SBC 3 starts relatively high in stiffness at low temperatures, but above 50 °C a severe drop in modulus takes place, which means a severe softening of the material, and almost complete loss of properties at 120 °C.

SBC 2 performs similar in DMA to the reference TPV, but this is not a guarantee for good elasticity at increased temperature as shown in the compression set measurements in **figure 4**. For static applications SBCs may perform reasonably, but in case of deformation or pressure TPVs are the material of choice. Parts will be under pressure in applications where hot fill is applied, steam sterilisation is being used or where parts end up in dishwashers. In steam sterilisation processes, it is typical to see temperatures up to 120 °C or even 130 °C.

Maximum continuous use temperatures (unloaded) for standard TPVs are in the range of 125 °C to 135 °C, with good retention of properties. For standard SBCs maximum

continuous use temperatures (unloaded) of 80 °C to 100 °C are reported.

4. Conclusion

With a clear trend towards increasing demands with respect to higher temperatures and need for improved chemical resistance, Sarlink TPVs have become the best choice when a soft touch grip or an elastic seal is needed with excellent durability, good chemical resistance and very good performance at increased temperatures, especially in contact with aqueous food.

5. Future

With excellent sealing and soft touch performance, unlimited possibilities in appearance and part design, and good retention of properties after dishwashing and exposure to high heat, Sarlink TPVs are ready to face the increasing demands for high temperature and chemical resistance in food contact applications.

(All SBC based blends tested and described in this article are commercially available materials currently being used in food contact applications.)

Fig. 5:
DMA of commercially used soft food contact materials

