Lenistat lubricating hydrophilic additive

Lenistat is a polymer material for injection molding and extrusion. The unique feature of Lenistat is that the molded devices are hydrophilic directly from the molding machine or the extruder. No expensive and complex hydrophilic coating process is needed.

Lenistat is developed for single use medical devices such as intermittent catheters.

Lenistat features

- Devices are hydrophilic directly from the molding machine or extruder.
- Devices become instantly lubricating when exposed to water.
- Simpler production and significantly reduced production cost
- Lenistat is delivered as a masterbatch in pellet form ready for mixing with TPE/TPU pellets before moulding/extrusion.
- Lenistat functions with elastomers between Shore A 30 and 75.
- Can be used with standard injection molding machines and standard extruders.
- Long functional life (10+ years) thus easily supporting a 2 year shelf life of a device.
- Biocompatible

Intended for 2K-Injection moulding and co-extrusion

While TPE/TPU with Lenistat can be moulded as a single material device and extruded as a single material tube, it is intended for 2K-Injection moulding and co-extrusion. Using these two-material technologies it is possible to place the lubricating Lenistat material precisely where it is needed. For 2K-Injection moulding the designer have complete freedom in the design and placement of the lubricating material. For co-extrusion the lubricating material should be on the outside of the tube.

In 2K-Injection moulding and co-extrusion the base elastomer and the elastomer mixed with Lenistat, should either be the same elastomer or an elastomer of the same type with a lower Shore A grade. The same elastomer type ensures excellent adhesion between the two materials. A lower Shore A grade of the elastomer mixed with Lenistat (90 Shore A), enables matching of the hardness of the two materials. This reduces mechanical stress in the device and give a better feel when handling the device.

Lenistat hydrophilic characteristics

An elastomer with the Lenistat additive will look and feel as a dry elastomer when extruded or moulded, it is not lubricating, greasy or sticky. When wetted with water the material instantly becomes very lubricating.
The durability will be short to medium depending on the Lenistat concentration and the Shore A grade of the elastomer. Lenistat is not suitable for devices requiring lubrication for extended periods of time.
If the material is first wet and lubricating and then allowed to dry, then it will go from lubricating through greasy to sticky as it dries. Lenistat is not recommended for applications where the device will dry.

Recommended Lenistat concentration

The optimum concentration of Lenistat ranges between 15% and 50%, depending on the TPE/TPU material, the device and the application. The best concentration for a specific device must be determined experimentally.

General guidelines

Elastomer Shore A grade

The harder the elastomer the more Lenistat is required for proper lubrication.

Shore A <25:	Not recommended
Shore A 30:	15% - 25% Lenistat
Shore A 40:	15% - 30% Lenistat
Shore A 50:	15% - 35% Lenistat
Shore A 60:	20% - 40% Lenistat
Shore A 70:	30% - 50% Lenistat
Shore A >75:	Not recommended

These ranges are based on our experience and is a good starting point for optimization, but the optimum concentration for a given device may be outside the listed ranges. Since lubrication is to some extent subjective then optimization must always be performed.

Too low Lenistat concentration

When the Lenistat concentration is too low the surface will not be sufficiently lubricating and/or the durability may be too short.

Too high Lenistat concentration

When the Lenistat concentration is too high the wetted surface will give off hydrophilic material that sticks to contacting surfaces. This material is safe and does not pose any risk, but it likely gives an unpleasant user experience.

Recommended elastomer

Lenistat works well with most TPE and TPU materials in the mid-range Shore A. Lenistat has a Shore A of 90, so Lenistat will make the compound material harder than the elastomer. This can be compensated by choosing a softer elastomer than what is intended for the device. Some experimentation must be expected for best performance.

Material compatibility

Lenistat is compatible with most elastomeric materials, but since we cannot test all materials then a specific material must be verified for compatibility.

- All tested TPE materials based on PP have been compatible, but some are much better than others.
- Most tested TPU materials have been compatible.

A material is compatible if it can mould/extrude, and the resulting device is homogenous and lubricates when wet.

Processing guidelines

Temperature settings

Lenistat can be moulded and extruded in the range 150°C to 240°C, so likely the optimum temperature will be determined by the properties of the elastomer.

Cooling for extrusion

Extruded tubes cannot be water cooled! Lenistat becomes lubricating as soon as it contacts liquid water, so water-cooling is not possible when extruding. Attempting water cooling will give a lubricating or sticky tube and neither are good for downstream handling.

Extruded tubes can be air-cooled or cooled in a standard bath where the water is replaced with PEG-400.

Other additives

Lenistat is compatible with most colorants and mould release agents, but it is important to verify compatibility when adding anything to the material. Due to the hydrophilic nature of Lenistat colorants may be released from the material during use.

Storage, disposal and safety

Storage

Pure Lenistat and Lenistat compounds are stable in normal humidity air but will get sticky in humid air (>80% RH). To ensure stability and to prevent premature activation of Lenistat, we recommend storing Lenistat devices and pellets dry and in sealed plastic bags. To avoid condensation of water on the Lenistat pellets, the material should be given time to reach room temperature before opening the plastic bag.

Disposal

Lenistat may be included with other waste containing similar plastic materials to be discarded for destruction or reclaim in accordance with local state and federal regulations. It is the responsibility of the customer to ensure the disposal of Lenistat is made in observance of all applicable environmental regulations.

Environmental, Health and Safety

Lenistat in both pellet and molded part form, is biocompatible and completely safe. No safety precautions are needed, but we don't recommend getting Lenistat dust into eyes/lungs or consuming it. Like any other plastic material, Lenistat will decompose very slowly in nature and thus accumulate. For this reason, Lenistat shouldn't be released in nature or other uncontrolled environments.

Warranty

The information in this datasheet is based on our experience and is, we believe to be reliable, but may not be complete. We make no guarantee or warranty, expressed or implied, regarding the information, use, handling, storage, or possession of this product, or the application of any process described herein or the results desired, since the conditions of use and handling of the product is beyond our control.