Fachverlag für die Polymerindustrie

Made to measure for medical applications

Sensitisation testing is recommended for all medical device categories according to the ISO 10993-1 guideline, since exposure or contact to even minute amounts of potential leachables can result in allergic or sensitisation reactions. The Mediprene TPE compounds of Elasto have now been classified as non-sensitisers. In addition, the company has introduced a long-term supply guarantee for a number of their medical compounds.

No sensitisation potential found in Mediprene compounds

No sensitisation potential

LAB Research, Hungary, carried out an independent skin sensitisation study on a representative **Mediprene** compound. The study was performed in accordance with EN ISO 10993–10 "Tests for Sensitisation and Irritation." The Mediprene compound was shown to have no sensitisation potential and classified as a non-sensitiser, according to current EU regulations.

Elasto has been supplying TPEs for skin contact applications for many years. The company said that it has never experienced sensitisation reactions among customers or end-users. "Close partnerships with our medical customers, a broad and deep understanding of medical device requirements, standards and functionality, this is what we offer our medical customers," commented Niklas Ottosson, medical technical manager at Elasto. "We have a strong heritage in the medical device market and are continuously working to expand our product offering. We support our customers by proving the performance of our products through carrying out relevant testing according to medical standards and pharmacopoeias." In addition to the sensitisation test, representative Mediprene grades have already passed cytotoxicity tests according to ISO 10993-5 and biocompatibility tests according to USP Class VI.

Supply guarantee

Product reliability and formulation stability are critical requirements for the medical device manufacturer. For a number of its Mediprene compounds Elasto has introduced a long-term supply guarantee. Conny Karlsson, medical key account manager explains: "Through the good co-operation and close dialogue we have with our raw material suppliers we have achieved agreements that will ensure a two year availability of unchanged product (excluding force majeure situations). Additionally, should a feedstock material be discontinued, we will also be able to cover the forecasted two year compound volume of our customers, allowing for qualification of a new material".

Flame retardant Dryflex grade for a cable box

Elasto said, it has worked with its suppliers to define what a change is, they agreed that notification only in cases of changes to raw material specification is not sufficient. Any change of the chemical composition of the raw materials also needs to be announced by the supplier. The long-term supply guarantee includes the Mediprene S, adhesion and oil-free series.

Mediprene thermoplastic elastomers are sterilisable with gamma, EtO and steam. They are PVC, silicone, and latex-free. Applications include medical tubing, IV systems, catheters, intubation and respiratory equipment, resealable membranes, drip chambers, and wound care products.

New flame-retardant grades

Besides the Mediprene series Elasto will showcase at K its **Dryflex** compounds. They are available in hardnesses ranging from 0 Shore A to 65 Shore D. Several applications from the automotive, consumer, construction and sports markets where these compounds have simplified production and added-value with soft-touch appeal will be shown. Recent developments include flame-retardant materials which are halogen, chlorine, and antimony-free, low smoke and are RoHS compliant.

Niklas Ottosson will present a paper on medical grade TPEs at the iSmithers Rapra Thermoplastic Elastomers 2010 conference, 26?–?27 October in Cologne, Germany.

Adresse:
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