Delivering sustainability

Eastman and Carolex introduce Eastman Eastalite™ copolyester to the European rigid medical packaging market.

Eastman has teamed with VitasheetGroup-Carolex to introduce the European market to an opaque, sustainable, cost-effective, and styrene-free alternative to high-impact polystyrene (HIPS): Eastman Eastalite™ copolyester.

"We've had a long history of working with Eastman," said Laurent Bouchet, commercial director, VitasheetGroup-Carolex. "So we trusted the team's experience while venturing into this new material and are intrigued by the possibilities. Eastalite is the first step toward creating lightweight packaging; and the unique product will open new opportunities for our specific medical applications."

With a cleaner cut than HIPS, Eastalite is a BPA-free opaque-foamed copolyester resin that can be processed with minimal generation of particulates or angel hair—saving manufacturers processing and inspection time, reducing waste and cleaning, and lowering costs. Other advantages include better hinge life, faster processing, and lightweighting opportunities.

Eastalite is best suited for applications in which lightweighting and other sustainable attributes are part of their fitness-for-use requirements, including work-in-progress trays, thermoformed pharmaceutical packaging, and packaging for economical medical devices or kits. It is made without materials of concern, including butadiene, bisphenol A (BPA), bisphenol S (BPS), *ortho*-phthalates, or halogens such as chlorine or bromine.

"Eastman Eastalite™ copolyester provides brand owners and medical device manufacturers with a styrene-free and easy-to-use material that comes at a price comparable to HIPS," said Ferdi Faas, market development manager, Eastman Chemical Company. "Carolex, being the first European extruder to use this new material, is now ahead of the competition by providing its customers more value with less environmental impact."

For more information, visit www.eastman.com/medical.

EASTMAN

The results of insight™

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Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.