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Biocompatibility study for Eastman Tritan™ EX401 copolyester

Eastman has developed a protocol to evaluate the biocompatibility of materials intended for infant-care applications based on steam sterilization. The following is a brief description of the testing, including the results achieved by Eastman Tritan™ EX401 copolyester. For additional information on the study, please contact Eastman at 1-800-327-8626.

Cytotoxicity*

An agar diffusion test was conducted to evaluate the potential biological reactivity of mammalian cells in vitro. Mammalian cells were selected for the test because of their sensitivity to leachable cytotoxic substances. Results: There was no biological reactivity observed at 48 hours post-exposure. Under accepted guidelines, these results indicate that Eastman™ Tritan EX401 copolyester is non-cytotoxic.

Sensitization reactions*

A direct-contact Buehler sensitization test was conducted to evaluate potential to produce skin sensitization in mammalian tissue in vivo. Topical application was selected because it represents a likely route of human exposure for infant-care products. Results: No skin reactions or overt signs of toxicity were detected. Eastman Tritan™ EX401 copolyester is not considered a skin sensitizer.

Skin irritation responses*

A primary skin irritation test was conducted to evaluate the potential to produce primary dermal irritation after a single topical exposure. Dermal exposure was selected because it represents a likely route of human exposure for infant-care products. Results: There were no signs of erythema (redness) or edema (swelling) at any point during the observation period. Eastman Tritan™ EX401 copolyester is considered a negligible irritant.

**All studies conducted in compliance with the current FDA 21 CFR, Part 58 — Good Laboratory Practice for Non-Clinical Laboratory Studies.*

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The results of **insight**™

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Material 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 in order 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 (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon 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 upon 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.

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