

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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