



Dear Valued Customer,

Biocompatibility of the ingredients in *FX0035-PA11 Masterbatch*, LDR 10:1 compounds were tested in representative compounds at a Let Down Ratio of 10:1. Testing was performed by a third party (NAMSA) under ISO 13485 conditions. A summary of the tests and results are below:

USP Acute Systemic Toxicity Study in the Mouse:

"The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Study in the Rabbit:

The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit:

The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 4 g:20 mL and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI."

The test results are specific to the representative compounds prepared. Any further extrapolation of the results would be the responsibility of the end user of the compound(s) containing the above-mentioned Masterbatch compound. It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations. Foster corporation makes not representation, promise, or express or implied warranty concerning the suitability of Foster's products for use in any medical device.

If you have any questions or require any additional information, please do not hesitate to contact the undersigned.

Respectfully Submitted,

Foster Regulatory Support
regulatory@fostercomp.com

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Foster Corporation

Headquarters: 45 Ridge Road ▪ Putnam, CT 06260 ▪ P: 860-928-4102 ▪ F: 860-928-4226
Foster West: 4336 Losee Road ▪ Suite 7 ▪ North Las Vegas, NV 89030 ▪ P: 702-644-4880 ▪ F: 702-644-5819
info@fostercomp.com ▪ www.fostercomp.com