Dear Valued Customer,

Please note that Foster has not performed testing on the individual pigments utilized for the below mentioned product line. Testing was only completed on the carrier resin.

The biocompatibility of the carrier resin used to formulate Foster's MediBatch™ Color Concentrates were tested by a third party testing service (NAMSA) under ISO 13485 conditions. A summary of the tests and results are below:

"The test article, MediBatch™ carrier resin, was evaluated for systemic toxicity in mice in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted in alcohol saline, polyethylene glycol, 0.9% sodium chloride USP solution, and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Day 3. **There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.**

The potential of the test article, MediBatch™ carrier resin, to cause irritation following intradermal injection in rabbits was evaluated based on the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG). A 0.2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of two animals. Similarly, the corresponding control was injected on the left side of the back of each animal. Observations for erythema and edema were conducted at 24, 48, and 72 hours after intracutaneous injection. **There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements.**

The test article, MediBatch™ carrier resin, was implanted in to the muscle tissue of rabbits to evaluate the local tissue response in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. Implant test articles were sterilized by ethylene oxide and then degassed for 15 days and negative control articles were sterilized by ethylene oxide and then degassed for 13 days. The test article and negative control were intramuscularly implanted and animals were euthanized 7 days later. Muscle tissues were excised and the implant sites were examined macroscopically. **The microscopic reaction was not significant as compared to the negative control article. The implanted test article met the USP requirements."**

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the compound(s) containing the above mentioned lubricant package. 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,

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