RE: Biocompatibility of LSR 2742

Thank you for your interest in the Momentive Performance Materials product LSR 2742.

In response to your above-mentioned query, we would like to inform you that a representative sample of LSR 2742 has been screened for ISO 10993 (Part 5, 6, 10, and 11) and USP Class VI testing (United States Pharmacopeia 34, National Formulary 29, 2011. <88> Biological Reactivity Test, In Vivo) requirements.

The product sample met the requirements of the following tests:

- Systemic Injection Test (USP Class VI and ISO 10993)
- Intracutaneous Toxicity Test (USP Class VI and ISO 10993)
- Intramuscular Implantation Test (USP Class VI and ISO 10993)
- Agar Diffusion (ISO 10993)
- MEM Elution (ISO 10993)

These test results are based on single lots of the Momentive materials. Although a lot-to-lot variance would not be expected to show different test results, these data should not be construed as a warranty of fitness for use. Prior to use for any application other than an industrial use, the user has the sole responsibility for determining the suitability of these products for any such application. Momentive Performance Materials has not established a "master file" at FDA.

Momentive Products are intended for use in the manufacture and/or formulation of products and they are not intended for direct consumer use. Please also note that Momentive Performance Materials has a long-standing policy on participation in certain product applications. Momentive may provide bulk raw materials to customers formulating or fabricating products for health care, personal care or other human body contact applications and may provide formulation recommendations and processing assistance in connection with those raw materials. Momentive will not knowingly promote the use of its products or sell to applications in which its products are implanted into the human body for 29 days or longer, are injected into the body, or used for contraceptive purposes. Momentive will carefully evaluate participation in applications, which involve exposure to infants, children and pregnant or nursing mothers. It is the sole responsibility of the purchaser to select a particular Momentive product and determine its suitability for an application and to comply with all
applicable statutory, regulatory, compatibility and industry requirements and standards for testing, safety, efficacy and labeling.

Do not hesitate to contact me if you have any questions.

Sincerely,

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