

## Momentive Performance Materials Inc.

260 Hudson River Road Waterford, NY 12188 momentive.com

10/12/2015

Rick Tardiff Casco Bay Molding 32 Smada Drive Sanford, ME 04073

RE: Biocompatibility of LIM6071

Dear Mr. Tardiff,

Thank you for your interest in the Momentive Performance Materials product LIM6071.

In response to your above-mentioned query, we would like to inform you that a representative sample of LIM6071 has been screened for USP Class VI testing requirements under Good Laboratory Practices (GLP):

The product sample met the requirements of the following tests:

- · Systemic Injection Test
- · Intracutaneous Toxicity Test
- · Intramuscular Implantation Test
- · Agar Diffusion
- · MEM Elution
- · Primary Skin Irritation Study
- · Hemolysis Rabbit Blood
- Sensitization
- · Intramuscular Implantation Subchronic (30 days)

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.

Please also note that Momentive Performance Materials has a long-standing policy on participation in certain product applications. Momentive is a supplier of industrial grade raw materials. 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,

## Shahzad Arshad

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