

5/8/2017

Grand Mega Technologies Development (Shenzhen) Limited Teamsan Chemical Limited Shenzhen, Guangdong

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 Pharmacopoeia 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,

Shahzad Arshad

Toxicologist Product Stewardship 260 Hudson River Road Waterford, NY 12188 518-233-3722 Fax: 518-233-2626 Shahzad.Arshad@Momentive.com

THE MATERIALS AND PRODUCTS OF THE BUSINESSES MAKING UP THE MOMENTIVE PERFORMANCE DISCLAIMER: MATERIALS("MOMENTIVE"), ITS SUBSIDIARIES AND AFFILIATES, INCLUDING WITHOUT LIMITATION ARE SOLD SUBJECT TO MOMENTIVE'S STANDARD CONDITIONS OF SALE, WHICH ARE INCLUDED IN THE APPLICABLE DISTRIBUTOR OR OTHER SALES AGREEMENT, PRINTED ON THE BACK OF ORDER ACKNOWLEDGMENTS AND INVOICES, AND AVAILABLE UPON REQUEST. ALTHOUGH ANY INFORMATION, RECOMMENDATIONS, OR ADVICE OFFERED IN CONNECTION WITH THE SALE OF ANY MATERIALS AND PRODUCTS IS GIVEN IN GOOD FAITH, MAKES NO WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, (I) THAT THE RESULTS DESCRIBED WILL BE OBTAINED UNDER END-USE CONDITIONS, OR (II) AS TO THE EFFECTIVENESS OR SAFETY OF ANY DESIGN INCORPORATING MOMENTIVE MATERIALS, PRODUCTS, RECOMMENDATIONS OR ADVICE. EXCEPT AS PROVIDED IN MOMENTIVE'S STANDARD CONDITIONS OF SALE, MOMENTIVE AND ITS REPRESENTATIVES SHALL IN NO EVENT BE RESPONSIBLE FOR ANY LOSS RESULTING FROM ANY USE OF ITS MATERIALS OR PRODUCTS. Each user bears full responsibility for making its own determination as to the suitability of MOMENTIVE'S materials, products, recommendations, or advice for its own particular use. Each user must identify and perform all tests and analyses necessary to assure that its finished parts incorporating MOMENTIVE'S materials or products will be safe and suitable for use under end-use conditions. Nothing in this or any other document, nor any oral recommendation or advice, shall be deemed to alter, vary, supersede, or waive any provision of MOMENTIVES'S Standard Conditions of Sale or this Disclaimer, unless any such modification is specifically agreed to in a writing signed by MOMENTIVE. No statement contained herein concerning a possible or suggested use of any material, product or design is intended, or should be construed, to grant any license under any patent or other intellectual property right of MOMENTIVE PERFORMANCE MATERIALS or any of its subsidiaries or affiliates covering such use or design, or as a recommendation for the use of such material, product or design in the infringement of any patent or other intellectual property right.