



Momentive Performance Materials Inc.
260 Hudson River Road
Waterford, NY 12188
momentive.com

June 12, 2018

Karin Richter
Werkstoffe und Prozesse
Institute for International Product Safety GmbH
Eaton Electrical Sector EH-IPL-W Hein-Moeller-Straße 7-11
53115 Bonn

Re: Compliance of LSR 2050 with 21 CFR 177.2600-Rubber articles intended for repeated use

Dear Karin Richter,

Thank you for your interest in the Momentive Performance Materials product LSR2050.

With regard to your query on the compliance of LSR 2050 with U.S. Food and Drug Administration (FDA) regulations, we would like to inform you that this product is compositionally compliant with 21 CFR 177.2600 – substances employed in the preparation of rubber articles intended for repeated use. Accordingly, FDA regulations for rubber articles intended for repeated use allow the use of LSR 2050, in manufacturing rubber articles that are intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food provided such articles are manufactured in accordance with other applicable FDA requirements. These requirements include the following provisions:

1. Articles are manufactured in accordance with Good Manufacturing Practice as defined by U.S. FDA regulations and guidance. Such practices may include post-baking the rubber article, depending upon the article and application. Momentive recommends appropriate post-baking of the rubber articles.
2. Substances employed in the preparation of rubber articles conform to applicable regulations promulgated by the FDA and/or other agencies or Trade Organizations having jurisdiction. Momentive Performance Materials will support applications to various agencies or Trade Organizations, when requested and where appropriate.
3. The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.
4. Finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.
5. Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

6. Rubber articles intended for repeated use in contact with aqueous food and fatty foods meet the extractive limitations as specified in 21 CFR 177.2600(c).

Momentive has on file, data which indicates that a representative sample of LSR 2050 when properly compounded and cured, meets extractive limitations for use in contact with aqueous foods and fatty foods. Extractives have been evaluated at reflux temperatures but not under autoclave conditions.

Prior to the use of this product for a food contact application, it is the responsibility of the fabricator to determine that their end-use product conforms to the specifications and limitations of this regulation, under their specific curing and post-baking conditions of use. See 21 CFR 177.2600 for details of extractive limitations and other requirements.

Prior to use for any application other than an industrial use, the user has the sole responsibility of determining the suitability of this product for any such application. Momentive Silicone rubber products are not designed for permanent implantation into the human body.

If you have any further questions, please feel free to contact me.

Sincerely,

Shahzad Arshad

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

DISCLAIMER: THE MATERIALS AND PRODUCTS OF THE BUSINESSES MAKING UP THE MOMENTIVE PERFORMANCE 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 MOMENTIVE'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.