



Momentive Performance Materials Inc.
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Michael Hartmann
Senior Technical Sales & Product Manager
Synthetic Rubber, Rubber Chemicals
Business Unit Elastomers & Additives
Nordmann, Rassmann GmbH
Kajen 2 • 20459 Hamburg • Germany

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

Dear Michael Hartmann,

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

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