



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

8/28/2019

Mrs. Andrea Loskamp  
DARMSTÄDTER GmbH  
Rudolf-Diesel-Straße 30  
46485 Wesel  
Germany

**Re: Compliance of LSR2560 with 21 CFR 177.2600-Rubber articles intended for repeated use**

Dear Mrs. Andrea Loskamp,

Thank you for your interest in the Momentive Performance Materials product LSR2560.

With regard to your query on the compliance of LSR2560 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(c) – 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 LSR2560 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

Users of this product are advised to review 21 CFR 177.2600 for details of extractive limitations and other requirements and assure themselves that the end product passes these requirements for FDA compliance, under their specific curing and post-baking conditions of use.

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.

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

Sincerely,

*Shahzad Arshad*

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Product Stewardship  
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