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Confirmation of food contact compliance for ELASTOSIL® M 4670 A/B

We herewith confirm that the ingredients of **ELASTOSIL® M 4670 A/B** comply with the positive lists of the below mentioned regulations which means that the product is suitable for the manufacture of food contact articles in compliance with article 3 of Regulation (EC) No. 1935/2004. Compliance with the requirements of Regulation (EC) No. 1935/2004 for the food contact material or article on limitations for migration or extraction and volatiles, and the effect on taste and smell of the food has to be ensured by the producer of the food contact material or article.

1. Germany: BfR XV. Silicones:

Extractables and volatiles may not exceed 0.5%.

<u> 2. France: Arrêté du 25 novembre 1992:</u>

Volatile components may not exceed 0.5%. Total migration is limited to 60 mg/kg.

3. USA: FDA 21 CFR §177.2600 Rubber articles intended for repeated use:

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.

Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square

inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during

the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

Please note that **ELASTOSIL® M 4670 A/B** contains residual toluene as a technical impurity at low level (< 0.1%) which has to be **completely removed** from the final food contact article.

Wacker-Chemie AG

Burghausen, December 20, 2011

Dr. C. Burger

GB-S-IMS Manager Product Stewardship 1

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility for compliance with specific limits on migration/extraction or volatiles resides with the manufacturer of the finished product.

This information is considered accurate and reliable as of the date appearing above and is presented in good faith. It is valid from the date of issue unless legal changes become effective. Because use



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