

## Confirmation of food contact compliance for WACKER ELASTOSIL® M 4601 A/B

We herewith confirm that **WACKER ELASTOSIL® M 4601 A/B** is suitable for use in accordance with the Recommendation XV. Silicones of the BfR (former BgVV) and with the FDA §177.2600 "Rubber articles intended for repeated use" provided that the material is appropriately cured/postcured so that the following restrictions are met:

## BfR XV. Silicones:

Extractables and volatiles may not exceed 0.5%. The cured elastomer may not change the food concerning taste and odour.

## FDA §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.

In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

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 the a.m. requirements resides with the manufacturer of the finished product.

Wacker-Chemie AG

Dr. C. Burger 

GB-S-IMS Manager Product Stewardship 1

Burghausen, April 24, 2008

This certificate is valid unless legal changes become effective.