

## Food contact compliance statement for WACKER ELASTOSIL® E 43 transparent

We herewith confirm that food contact articles manufactured from **WACKER ELASTOSIL® E 43 transparent** are suitable for use under under the below mentioned regulations provided that the final material is appropriately cured/postcured so that the following restrictions are met:

2. France: Arrêté du 25 novembre 1992:
Volatile components may not exceed 0.5%. Total migration is limited to 60 mg/kg.

3. USA: FDA21 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.

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.

**ELASTOSIL® E 43 transparent** is not in compliance with the recommendations of the BfR (former BgVV).

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 GmbH

Burghausen June 15, 2005

Dr. C. Burger (

GB-S-IMS Manager Product Stewardship 1

This certificate is valid unless legal changes become effective.