

Statement on Suitability for use under Food contact Regulations for ELASTOSIL® E 43 N transparent/white

It is hereby confirmed that the ingredients of **WACKER ELASTOSIL® E 43 N transparent/white** are in compliance with the below mentioned national positive lists.

Accordingly, the products are 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, especially the suitability of the material or article for the intended use, the observance of any given limitations, the effect on taste and smell of the food has to be ensured by the producer of the final food contact material or article as it is placed on the market.

1. Germany: BfR XV. Silicones:

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

2. France: Arrêté du 25 novembre 1992:

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

2. USA: 21 CFR

§ 175.105 Adhesives

§ 175.300 Resinous and Polymeric Coatings:

Extractive limits under 175.300 (c) – (e) have to be observed.

§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.

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Please note that the product contains low levels of residual toluene (< 0.1%) and propanol (< 1%) which must be **completely** removed from the food contact article.

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 additional requirements as cited above resides with the manufacturer of the finished product.

Wacker-Chemie AG

A handwritten signature in black ink, appearing to read "Burger", with a long, sweeping horizontal line extending to the right.

Dr. C. Burger
GB-S-IMS Manager Product Stewardship 1

Burghausen, May 6, 2014

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