WACKER

ELASTOSIL® M 4641 A&B

U.S. Federal Food, Drug and Cosmetic Act (FDA) Food Contact Conformance Evaluation (21 CFR Parts 170-199)

The above product as sold by WACKER has been evaluated as compliant for the food contact applications listed below, based on the known composition and raw materials used in production. Any modifications or additional processing may impact such conformance.

Food Contact Applications	
Regulation	**Limitations***
§177.2600 – Rubber articles intended for repeated use	The finished article must meet the extractive limits described in paragraphs (e) and (f) of Section 177.2600.

The above product as sold by WACKER is not intended for direct addition to food.

*It is the responsibility of the downstream users to assess suitable purity under 21 CFR 174.5 (“General provisions applicable to indirect food additives “). Compliance with this requirement mandates that the exposure to substances that may remain in the finished article: (a) do not adversely affect the organoleptic properties of the finished article; and (b) do not render the food contacting the article unsuitable or injurious to health. This may require a determination of the levels of any impurities that may be present in the finished article. Please contact your WACKER representative for more information regarding expected impurities in this product.

The responsibility for compliance of finished food contact articles with FDA regulations resides with the manufacturer of the finished food contact article(s), including without limitation any required testing of these articles such as extraction or migration testing, compliance with any section limitations on the food types or conditions of use, and the obligation to use these materials in accordance with Good Manufacturing Practices (21 CFR 174.5).

The information herein applies only to the specific product referenced above as sold by WACKER as of the issuance date below and does not apply to use in any process or in combination with any other material.

This Conformance Evaluation does not imply that a finished article manufactured from the WACKER product is approved or considered safe by the FDA. Furthermore, this document is provided at the request of and without charge to our customers. Accordingly, WACKER does not guarantee or warrant any information herein and disclaims any and all liability for its use.

This Conformance Evaluation is issued as of November 5, 2026 and expires three years after issuance.

Please contact the WACKER InfoLine at info.usa@wacker.com if you require further information.

Material number: 60063603

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