

# ELASTOSIL<sup>®</sup> Silicone Rubber for Food Contact Applications

## 1. Recommendation of BfR (Germany)

Silicone rubber articles produced from the following products comply with the Recommendation Chapter "XV. Silicone" (01.06.2007) of Bundesinstitut für Risikobewertung (BfR) provided that (a) both extractables\* and volatiles<sup>†</sup> do not exceed 0,5%,<sup>‡</sup> (b) no peroxides can be detected<sup>§</sup> and (c) the material does not change the food regarding taste and odour. To meet these requirements proper cure and post cure conditions (4 h/200 °C, air exchange rate ≥ 120 l/min per kg silicone) are required.

ELASTOSIL<sup>®</sup> R 101/25, 35, 45  
ELASTOSIL<sup>®</sup> R 401/10–90  
ELASTOSIL<sup>®</sup> R 402/60, 65, 75  
ELASTOSIL<sup>®</sup> R 411/50–70  
ELASTOSIL<sup>®</sup> R 420/30–70  
ELASTOSIL<sup>®</sup> R 440/60  
ELASTOSIL<sup>®</sup> R 490/55  
ELASTOSIL<sup>®</sup> R 752/50  
ELASTOSIL<sup>®</sup> R 755/40, 60  
ELASTOSIL<sup>®</sup> R 780/80  
ELASTOSIL<sup>®</sup> R 830/45  
ELASTOSIL<sup>®</sup> R 861/60–80  
ELASTOSIL<sup>®</sup> R *plus* 4000/40–70  
ELASTOSIL<sup>®</sup> R *plus* 4001/40–80  
ELASTOSIL<sup>®</sup> R *plus* 4020/60  
ELASTOSIL<sup>®</sup> R *plus* 4105/40–70  
ELASTOSIL<sup>®</sup> R *plus* 4110/40–80  
ELASTOSIL<sup>®</sup> R *plus* 4305/30–90  
ELASTOSIL<sup>®</sup> R *plus* 4360/60  
ELASTOSIL<sup>®</sup> R *plus* 4366/60  
ELASTOSIL<sup>®</sup> LR 3003/03–85  
ELASTOSIL<sup>®</sup> LR 3003/10 TR  
ELASTOSIL<sup>®</sup> LR 3003/20 TR  
ELASTOSIL<sup>®</sup> LR 3003/30 R  
ELASTOSIL<sup>®</sup> LR 3003/30 CS  
ELASTOSIL<sup>®</sup> LR 3003/70 K4

\* Bundesgesundheitsbl **1961**, 12, 189–193.

<sup>†</sup> 61. Mitteilung; Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz **2003**, 46, 362–365.

<sup>‡</sup> Please note that the test conditions for measuring the weight loss depends on the application and service temperature.

<sup>§</sup> 58. Mitteilung; Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz **1997**, 40, 412.

ELASTOSIL<sup>®</sup> LR 3004/20–80  
ELASTOSIL<sup>®</sup> LR 3040/40+50  
ELASTOSIL<sup>®</sup> LR 3043/30–70  
ELASTOSIL<sup>®</sup> LR 3066/40, 60, 80  
ELASTOSIL<sup>®</sup> LR 3071/30–60  
ELASTOSIL<sup>®</sup> LR 7661, 7665  
ELASTOSIL<sup>®</sup> AUX GRUND G 790  
SILPURAN<sup>®</sup> 6000/10–70  
SILPURAN<sup>®</sup> 6400/40–60  
SILPURAN<sup>®</sup> 6600/40–60  
SILPURAN<sup>®</sup> 6700/40–60  
SILPURAN<sup>®</sup> 8000/40–70  
SILPURAN<sup>®</sup> 8020/40–70  
SILPURAN<sup>®</sup> 8030/40–70  
SILPURAN<sup>®</sup> 8060/40–70  
SILPURAN<sup>®</sup> 8461/60

Confirmations concerning the compliance of individual grades with the Recommendations of BfR can be provided by S-IMS (Dr. Burger) upon request. Certificates from an external institute are not available.

## **2. FDA CFR 21 § 177.2600 (USA)**

Silicone rubber articles produced from the following products comply with FDA CFR 21 § 177.2600 “Rubber articles intended for repeated use” provided that the following restrictions are met:

- (a) 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.
- (b) 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.

To meet these requirements proper cure and post cure (4 h/200 °C, air exchange rate ≥ 120 l/min per kg silicone) is required.

ELASTOSIL<sup>®</sup> R 101/25, 35, 45  
ELASTOSIL<sup>®</sup> R 401/10–90

ELASTOSIL® R 402/60, 65, 75  
ELASTOSIL® R 411/50–70  
ELASTOSIL® R 420/30–70  
ELASTOSIL® R 430/10+40+70 (+ BTB 2)  
ELASTOSIL® R 440/60  
ELASTOSIL® R 490/55  
ELASTOSIL® R 533/60  
ELASTOSIL® R 752/50  
ELASTOSIL® R 755/40  
ELASTOSIL® R 780/80  
ELASTOSIL® R 830/45  
ELASTOSIL® R 861/60–80  
ELASTOSIL® R *plus* 4000/40–70  
ELASTOSIL® R *plus* 4001/40–80  
ELASTOSIL® R *plus* 4020/60  
ELASTOSIL® R *plus* 4105/40–70  
ELASTOSIL® R *plus* 4110/40–80  
ELASTOSIL® R *plus* 4300/40+70 (+ BTB 2)  
ELASTOSIL® R *plus* 4305/30–90  
ELASTOSIL® R *plus* 4360/60  
ELASTOSIL® LR 3003/30–85  
ELASTOSIL® LR 3003/20 TR  
ELASTOSIL® LR 3003/30 R  
ELASTOSIL® LR 3003/30 CS  
ELASTOSIL® LR 3003/70 K4  
ELASTOSIL® LR 3004/20–80  
ELASTOSIL® LR 3043/30–70  
ELASTOSIL® LR 3066/40, 60, 80  
ELASTOSIL® LR 3071/30–60  
ELASTOSIL® LR 7661, 7663, 7665  
ELASTOSIL® E 43  
SILPURAN® 6000/20–70  
SILPURAN® 6400/40–60  
SILPURAN® 6600/40–60  
SILPURAN® 6700/40–60  
SILPURAN® 8000/40–70  
SILPURAN® 8020/40–70  
SILPURAN® 8030/40–70  
SILPURAN® 8060/40–70  
SILPURAN® 8461/60

Silicone rubber articles that are not in direct food contact, e.g. oven door gaskets, are not regulated by FDA CFR 21 § 177.2600 “Rubber articles intended for repeated use”.

Confirmations concerning the compliance of individual grades with FDA § 177.2600 can be provided by S-IMS (Dr. Burger) upon request. Certificates from an external institute are not available.

