

Silicon rubber articles produced with ELASTOSIL[®] R and ELASTOSIL[®] LR series

Use as food contact material

Recommendation of BfR (former BgVV) XV "Silicones" (Germany)

Silicon rubber articles produced with

ELASTOSIL[®] R 101/25,35,45
ELASTOSIL[®] R 401/20-90
ELASTOSIL[®] R 402/60,65,75
ELASTOSIL[®] R 420/30-70
ELASTOSIL[®] R 440/60
ELASTOSIL[®] R 490/55
ELASTOSIL[®] R 752/50
ELASTOSIL[®] R 755/40,60
ELASTOSIL[®] R 780/80
ELASTOSIL[®] R 861/60-70
ELASTOSIL[®] R *plus* 4000/40-80
ELASTOSIL[®] R *plus* 4001/40-80
ELASTOSIL[®] R *plus* 4020/60
ELASTOSIL[®] R *plus* 4110/50-80
ELASTOSIL[®] R *plus* 4305/40-70
ELASTOSIL[®] R *plus* 4360/60-70
ELASTOSIL[®] LR 3003/10-80 A+B
ELASTOSIL[®] LR 3004/30-80 A+B
ELASTOSIL[®] LR 3005/30-70 A+B
ELASTOSIL[®] LR 3023/60 A+B
ELASTOSIL[®] LR 3043/40-60 A+B
ELASTOSIL[®] LR 3071/40,50 A+B
ELASTOSIL[®] LR 3094/50-60 A+B
ELASTOSIL[®] LR 7661, 7663, 7665 A+B

comply with the recommendation XV. silicones of BfR 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.

The products available as granulates contain an additive which is formally not listed in the recommendation XV. silicones of the BfR (Bundesamt für Risikobewertung). However this compound is completely evaluated by the SCF (Scientific Committee for Food) referring to SCF-List 0-4. Such components may be used for the manufacture of food contact materials according to the recommendations of the BgVV.

”KTW-Recommendation ” BGBl. 28, Nr. 12 (1985) (Germany)

Articles produced from the silicone rubbers

ELASTOSIL[®] R 401/40-80
ELASTOSIL[®] R 402/60
ELASTOSIL[®] R 420/40-70
ELASTOSIL[®] LR 3003/30 - 80 A+B
ELASTOSIL[®] LR 3004/30 - 80 A+B
ELASTOSIL[®] LR 3071/40 - 50 A+B

meet the requirements of this recommendation (classes C, D1, D2).

DVGW Worksheet W270 (Additional Requirement from KTW)

Articles produced from the silicone rubbers

ELASTOSIL[®] R 401/40-80
ELASTOSIL[®] R 402/60
ELASTOSIL[®] R 420/40-70
ELASTOSIL[®] LR 3003/30 - 80 A+B
ELASTOSIL[®] LR 3004/30 - 80 A+B
ELASTOSIL[®] LR 3071/40 - 50 A+B

FDA CFR 21 § 177.2600**"Rubber Articles Intended for Repeated Use" (USA)**

Food contact materials manufactured with the silicon rubbers of the ELASTOSIL® series

ELASTOSIL® R 101/25,35,45
ELASTOSIL® R 401/20-90
ELASTOSIL® R 402/60,65,75
ELASTOSIL® R 420/30-70
ELASTOSIL® R 440/60
ELASTOSIL® R 490/55
ELASTOSIL® R 533/60
ELASTOSIL® R 701/40-80
ELASTOSIL® R 750/40-50
ELASTOSIL® R 752/50
ELASTOSIL® R 755/40
ELASTOSIL® R 760/60-70
ELASTOSIL® R 780/80
ELASTOSIL® R 861/60-70
ELASTOSIL® R *plus* 4001/40-80
ELASTOSIL® R *plus* 4020/60
ELASTOSIL® R *plus* 4110/50-80
ELASTOSIL® R *plus* 4305/40-70
ELASTOSIL® R *plus* 4360/60-70
ELASTOSIL® LR 3003/10-80 A+B
ELASTOSIL® LR 3004/30-80 A+B
ELASTOSIL® LR 3043/40-60 A+B
ELASTOSIL® LR 3071/40,50 A+B
ELASTOSIL® LR 3471/40,50 A+B
ELASTOSIL® LR 7661, 7663, 7665 A+B
ELASTOSIL® E 43

comply with FDA §177.2600 „Rubber articles intended for repeated use: provided that the material is appropriately cured/postcured so that the following restrictions are met:

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.