

1. Europe:

As no harmonized European legislation on Silicones exists, these materials are subject to the Framework Regulation (EC) No. 1935/2004 and national provisions (Article 6). Provided appropriate processing, **ELASTOSIL® R 401/10 – 90 S or OH series** and their curing agents **ELASTOSIL® Crosslinker B, C1, C6, E and E 2** are suitable for the manufacture of food contact materials and articles under article 3 of the before mentioned Regulation. 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.

2. Germany:

The ingredients of **ELASTOSIL® R 401/10 – 90 S or OH series** and their curing agents **ELASTOSIL® Crosslinker B, C1, C6, E and E 2** are contained in the positive list of Recommendation XV. Silicones of the BfR.

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

If Bis(2,4-dichlorobenzoyl)peroxide (Crosslinker E) is used as curing catalyst, an SML (specific migration limit) of 5 mg/kg food or food simulant relating to the decomposition product 2,4-dichlorobenzoic acid, has to be met.

3. France:

The ingredients of **ELASTOSIL® R 401/10 – 90 S or OH series** and their curing agents **ELASTOSIL® Crosslinker B, C1, C6 and E** are in compliance with the positive list of the Arrêté du 25 novembre 1992.

Limitations: Total migration may not exceed 60 mg/kg food or food simulant, respectively, and volatiles are limited to 0.5%.

4. USA:

The ingredients of **ELASTOSIL® R 401/10 – 90 S or OH series** and their curing agents **ELASTOSIL® Crosslinker B, C1, C6, E and E 2** are in compliance with 21 CFR §177.2600 Rubber articles intended 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.