

DICOINSA S.L.

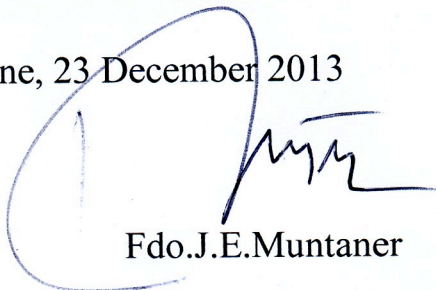
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We hereby CERTIFICATE that our silicone REF 401/60-E complies with all the specifications with food contact:

Bfr (Germany) Chapter XV
FDA CFR 177.2600 (USA)
1935/2004/ EC REGULATION
USP CLASS VI
WRAS (water regulations)

Barcelone, 23 December 2013



Fdo. J.E. Muntaner

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ELASTOSIL® 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" of Bundesinstitut für Risikobewertung (BfR) provided that (a) both extractables^{*} and volatiles[†] do not exceed 0,5%,[‡] (b) no peroxides can be detected[§] 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® R 101/25, 35, 45, 65
ELASTOSIL® R 401/10–90
ELASTOSIL® R 402/60, 65, 75
ELASTOSIL® R 411/50–70
ELASTOSIL® R 420/30–70
ELASTOSIL® R 440/60
ELASTOSIL® R 490/55
ELASTOSIL® R 752/50
ELASTOSIL® R 755/40, 60
ELASTOSIL® R 756/60 OH
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* 4305/30–90
ELASTOSIL® R *plus* 4360/60
ELASTOSIL® R *plus* 4366/60
ELASTOSIL® LR 3003/03–85
ELASTOSIL® LR 3003/10 TR
ELASTOSIL® LR 3003/20 TR
ELASTOSIL® LR 3003/30 R
ELASTOSIL® LR 3003/30 CS

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^{*} Bundesgesundheitsbl **1961**, 12, 189–193.

[†] 61. Mitteilung; Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz **2003**, 46, 362–365.

[‡] Please note that the test conditions for measuring the weight loss depends on the application and service temperature.

[§] 58. Mitteilung; Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz **1997**, 40, 412.

ELASTOSIL® LR 3003/70 K4
ELASTOSIL® LR 3004/20-80
ELASTOSIL® LR 3040/40-60
ELASTOSIL® LR 3043/30-70
ELASTOSIL® LR 3066/40, 60, 80
ELASTOSIL® LR 3071/30-60
ELASTOSIL® LR 7661, 7665
ELASTOSIL® AUX GRUND G 790
SILPURAN® 6000/10-70
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

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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® R 101/25, 35, 45

ELASTOSIL® 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 756/60 OH
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 3040/40+50
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

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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.

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Statement on suitability for Use under Food Contact Regulations for **ELASTOSIL® R 401/10 – 90 S or OH**

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.

Limitations:

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.

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SILICONES

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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.

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 further requirements like limits on extraction/migration or volatility resides with the manufacturer of the finished product.

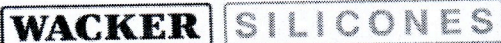
Wacker-Chemie AG

Burghausen, October 16, 2013


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

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Statement on Biocompatibility

The products **WACKER ELASTOSIL® R 401/30 - 90** have been tested according to USP Class VI and the 30, 40 and 80 duro grade materials additionally according to ISO 10993. **R 401/30 and 40** have a lower content of filler and can therefore be considered as the worst case materials referring to possible migration of hazardous compounds. **R 401/30, 40 and 80** have passed the ISO 10993 test series (haemocompatibility, cytotoxicity, 90-day-implantation, skin irritation and sensitization and pyrogenicity) without showing any adverse effects. We therefore firmly believe that the ISO 10993 results received with **R 401/30 and 40** will be representative also for the materials with the higher duro grades which have also passed the USP Class VI tests (acute systemic and intracutaneous toxicity, implantation) without showing any adverse effects.

This statement does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility for compliance of the finished article with existing legislation resides with the person(s) producing and placing the article on the market.

Wacker-Chemie AG

Burghausen, November 21, 2012

A handwritten signature in black ink, appearing to read "Burger", written over a horizontal line.

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

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