

Food Contact Compliancy

Filcoflex B.V. Netherlands hereby certifies that the following products (1) meet the requirements, and are suitable according to the here under listed (2) regulations and guidelines for the repetitive use in contact with foodstuff materials:

Filcoflex Silicone Sheet products to which this Declaration of Compliance applies (1)

- PKSR polyester knitted fabric silicone rubber 60°Shore A, 2mm thickness
- Translucent 60° Shore A silicone sheet material 1, 2, 3, 4, 5mm thickness



Rules and Regulations to which was tested (2)

Regulation (EC) 1935/2004

Materials and Articles intended to come in to contact with food.

Filcoflex B.V. certifies that in the manufacture of our materials (1) our raw material supplier and sheet manufacturer use elastomers & starting substances that comply with relevant requirements of Regulation (EC1935/2004).

REGULATION (EC) 10/2011

Regulation (EC) 10/2011 does not apply to silicone compounds since no plastics are added in these products.

COMMISSION REGULATION (EC) 2023/2006

Filcoflex, the raw material supplier and the sheet manufacturer all use a Quality Management System that operates full batch traceability of all ingredients and production processes from dispatch note to supplier batch identification. This means that we can therefor comply to 2023/2006.

Glass and Fork Logo

Filcoflex does not apply the glass and fork recommended food contact logo on any products at this time, due to the unavailability of a food safe ink that can be applied to silicone products.



Declaration of Compliance

EU Extraction testing

In the current absence of EU legislation which specifies the requirements to prove that a silicone article is safe for food contact, we have conducted extraction testing to the requirements of FDA21CFR 177.2600 "Rubber articles intended for repeated contact with food stuff" and BfR XV. Compliance with FDA21CFR shows that these grades are safe for food contact as required by EC1935/2004.

FDA

Filcoflex B.V. Netherlands certifies that materials (1) are compliant to FDA 21 CFR 177.2600. As specified by client, to determinate the amount of total extractives from rubber articles intended for repeated use for compliance with Food and Drug Administration Regulations These materials (1) have undergone a post cure heat treatment to ensure the removal of volatile chemicals that could cause contamination issues in food stuffs. Samples of manufactured materials (1) have been tested to and found to comply with the extraction/migration tests listed in 21 CFR 177.2600 (de) to (h). Typical results are indicated below.

Extraction testing

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Total extractives	Comment
Distilled Water 1st extraction	7.00 Hour(s)	Reflux temperature	<20.0 mg/inch ²	0.24mg/inch ²	PASS
Distilled Water 2nd extraction	2.00 Hour(s)	Reflux temperature	<1.0mg/inch ²	0.05mg/inch ²	PASS
n-Hexane 1st extraction	7.00 Hour(s)	Reflux temperature	<175.0mg/inch ²	<54.55mg/inch ²	PASS
n-Hexane 2nd extraction	2.00 Hour(s)	Reflux temperature	<4.0mg/inch ²	<3.68mg/inch ²	PASS

These results show that the materials (1) of solid silicone sheeting products are suitable for all food types defined in FDA 21 CFR 177.2600 (dry, aqueous, and fatty food stuffs).

As stated in 21 CR 177.2600 it is recommended that the manufactured article is thoroughly cleansed prior to first use in contact with food.

Filcoflex B.V.
The Netherlands
Luxemburgstraat 3
5171 PK
Kaatsheuvel

Website : www.filcoflex.com
E-mail : info@filcoflex.com
Telephone : +31 (0) 416 764 764
Fax : +31 (0) 416 764 763

BfR XV

The materials (1) of solid silicone elastomers have also been tested to and comply with the requirements of BfR XV "silicones".

GB 9685-2016 Chinese food contact legislation

Filcoflex B.V. Netherlands certifies that materials (1) are not compliant to GB 9685-2016 of the Chinese food contact legislation because it contains an ingredient above the permitted limit.

In GB 9685-2016 peroxide is restricted to a maximum of 0.2%.

Our materials (1) contain a higher percentage of peroxide off around 0.65%, making it comply to all other major food contact regulations.

*The polyester mesh inside PKSR is not tested to any above-described conditions, only the solid silicone elastomer.

Name: Werner van Loon
Function: Managing Director
Date: 25-05-2021

