

MATERIAL DATA SHEET



'A' TYPE FLUOROELASTOMER FDA COMPLIANT SHEET (SEE TEST RESULTS OVERLEAF)

PROPERTY	VALUE	TEST METHOD
COLOUR:	Beige	
FKM Type:	'A' Type Di-Polymer - 66% Fluorine Content	
Hardness:	64° Shore 'A' (+/-5°)	ASTM D2240
Specific Gravity	2.02 g/cm ³	
Tensile Strength	14 Mpa	ASTM D412
Elongation @ Break	250%	ASTM D412
Compression Set 22hrs @ 200°C	18%	ASTM D395 Method 'B'
Working Temperature	-10 to + 250°C	

- ★ We hereby declare that all of the ingredients in the rubber are compliant to the White List of FDA
- ★ We also declare that this material meets the migration values (extraction levels) of U.S. FDA 21 CFR 177.2600 regulations
- ★ Phthalate Free
- ★ Latex Free
- ★ Nitrosamine Free

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J-FLEX

High Performance Elastomer Sheetings & Manufactured Components

Units 1 & 2, London Road Business Park, Retford,
Nottinghamshire, DN22 6HG, United Kingdom

tel: +44 (0) 1777 712 400 fax: +44 (0) 1777 712 409
www.j-flex.co.uk



Independent testing carried out 16 August 2012 by SGS-CSTC Ltd – see relevant portions below:-

Test Report

No. SHAEC1214268901

Date: 22 Aug 2012

Date of Sample Received : 16 Aug 2012
Testing Period : 16 Aug 2012 - 22 Aug 2012
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.2600- Total Extractives	PASS

Signed for and on behalf of
SGS-CSTC Ltd.



Approved Signatory

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
1	SHA12-142689.001	Beige-yellow soft solid block

FDA 21 CFR 177.2600- Total Extractives

Test Requested : As specified by client, for compliance with Food and Drug Administration Regulations for determining the amount of total extractives from rubber articles intended for repeated use.

Test Method : As specified in FDA 21 CFR 177.2600.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Total Extractives</u>	<u>Comment</u>
Distilled Water	7.0hr(s)	Reflux temperature	20mg/inch ²	0.8mg/inch ²	PASS
Succeeding Extraction	2.0hr(s)	Reflux temperature	1mg/inch ²	<0.5mg/inch ²	PASS
n-Hexane	7.0hr(s)	Reflux temperature	175mg/inch ²	0.5mg/inch ²	PASS
Succeeding Extraction	2.0hr(s)	Reflux temperature	4mg/inch ²	<0.5mg/inch ²	PASS

PRODUCT INFORMATION

Date: November 3rd 2016

Statement on suitability for contact with foodstuff

We certify that our FKM Fluoroelastomer beige 65 is suitable to get in contact with foodstuffs, according to the following requirements:

- ⇒ Regulation 1935-2004
- ⇒ Order of 09/11/94 (JO of 02/12/1994)
- ⇒ Order of 09/08/05 (JO of 30/08/2005)
- ⇒ Order of 19/12/06 (JO of 29/12/2006)
- ⇒ Information notice of DGCCRF n° 2004-64 of 06/05/04

We certify that our material FKM Fluoroelastomer beige 65 does not contain substances subjected to restrictions in the above mentioned regulation. Global migration limits was tested under specific conditions, you can see results in table:

Conditions of contact with samples	Simulants	Observations of the sample	Observations of the simulant	Average to the nearest mg/dm ²
2 hours at 100°C	Acetic acid 3%	No modification	No modification	46,9
2 hours at 100°C	Ethanol 10%	No modification	No modification	3,6
2 hours at 100°C	Ethanol 20%	No modification	No modification	3,2
2 hours at 83°C	Ethanol 50%	No modification	No modification	2,6
5 hours at 60°C	Simulant of substitution	No modification	No modification	12,9

For the expected use, the following criteria of Article 7 of the Order of 09/11/94 are respected:

- free volatile organic substances,
- specific migration of nitrosamines and nitrosable substances into acetic acid 3%,
- specific migration of primary aromatic amines into acetic acid 3%,
- specific migration of formaldehyde into acetic acid 3%,
- specific migration zinc into acetic acid 3%,
- no positive reaction for peroxides according to the European Pharmacopeia method



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