

# J-FLEX MATERIAL DATA SHEET



**fluor-a-com**<sup>®</sup>  
only from J-Flex

FPM/FKM FLUOROELASTOMER  
FDA COMPLIANT SHEET  
(SEE TEST RESULTS OVERLEAF)



Food Safety  
EC No. 1935: 2004

PROPERTY	VALUE	TEST METHOD
COLOUR:	Blue	
FKM Type:	'A' Type Di-Polymer - 66% Fluorine Content	
Hardness:	64° Shore 'A' (+/-5°)	ASTM D2240
Specific Gravity	2.02 g/cm <sup>3</sup>	
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

Issue 3

November 2016



**J-FLEX RUBBER PRODUCTS**  
*Engineering Rubber Components & Specialised Sheeting Products*

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Independent testing carried out 18 June 2015 by SGS-CSTC Standards Technical Services Co. Ltd.  
 - see relevant portions below:-

## Test Report

No. SHAEC1511783904

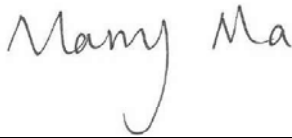
Date: 25 Jun 2015

Date of Sample Received : 18 Jun 2015  
 Testing Period : 18 Jun 2015 - 25 Jun 2015  
 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 Standards Technical Services Co. Ltd.



Approved Signatory

Test Results :

### Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	SHA15-117839.002	Blue solid sheet	Rubber

### FDA 21 CFR 177.2600- Total extractives

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

Test Method : With reference to FDA 21 CFR 177.2600.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 002 Total extractives</u>	<u>Conclusion</u>
Distilled water	7.0hr(s)	Reflux temperature	20mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS
Succeeding extraction	2.0hr(s)	Reflux temperature	1mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS
n-Hexane	7.0hr(s)	Reflux temperature	175mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS
Succeeding extraction	2.0hr(s)	Reflux temperature	4mg/inch <sup>2</sup>	<0.5mg/inch <sup>2</sup>	PASS

# PRODUCT INFORMATION

Date: November 3<sup>rd</sup> 2016

## Statement on suitability for contact with foodstuff

We certify that our FKM Fluoroelastomer blue 65 N°007701 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 blue 65 N°007701 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 <sup>2</sup>
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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