

FPM/FKM Fluoroelastomer FDA Compliant Sheeting

PROPERTY	VALUE	TEST METHOD	
Colour	Blue / Off-White		
FKM Type	'A' Type Di-Polymer - 66% Fluorine Content		
Hardness	70° (±5°) Shore 'A'	ASTM D2240	
Specific Gravity	2.0 (±0.1) g/cm ³	-	
Tensile Strength	≥9 MPa	ASTM D412	
Elongation at Break	≥180%	ASTM D412	
Compression Set 22hrs @ 200°C	<35%	ASTM D395 Method 'B'	
Working Temperature	-10 to +230°C		













Tolerances are Class 2

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.

Statement on suitability for contact with foodstuff

We certify that our FDA compliant FKM Fluoroelastomers are suitable to be 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 FDA compliant FKM Fluoroelastomers do not contain substances subjected to restrictions in the above mentioned regulation. Global migration limits were 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/dm²
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	D2 - vegetable oil	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%
- \bullet 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

Dimensional Tolerances: are typically class 3 as standard, unless otherwise stated. Class 2 and Class 1 tolerances on request, in most instances.

Disclaimer: All recommendations and information contained in this specification sheet are to the best of our knowledge correct. Since conditions of service are beyond our control, users must satisfy themselves that the products are suitable for intended use. No warranty is given or implied in respect of information or recommendations or that any use of products will infringe rights belonging to other parties. In any event or occurrence our liability is limited to the invoice value of our goods delivered to you. We reserve the right to change product design and properties without notice.

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