

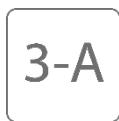
M SEALS CIPU-VI95

Purple FDA Compliant Polyurethane (H-PU)

MATERIAL DATA SHEET (Version 6.0 – 05.2022)



FDA compliant



3-A Sanitary



(EC) 1935/2004 compliant
(EC) 10/2011 compliant



ADI FREE

Description

M Seals material CIPU-VI95 is an FDA Compliant Hydrolysis resistant polyurethane material (H-PU) that is purple in colour and has been modified to provide good chemical resistance in food contact applications where the most common Clean-In-Place (CIP) fluids are used. The material has been successfully extraction tested in accordance with FDA and EC 10/2011 requirements for materials in repeated contact with food and meets the requirements of 3-A sanitary standard class II.

These fantastic attributes make CIPU-VI95 an excellent choice for seals and other parts which may require excellent chemical and/or fluid compatibility while working in food and beverage applications.

Physical Properties

Property	Test method	Unit	Typical Value
Colour			Purple
Density	ISO 1183-1	g/cm ³	1.16
Hardness	DIN 53505	Shore A	95 (+/-3)
Tensile strength	DIN 53504	MPa	≥45
Elongation at break	DIN 53504	%	≥300
Modulus 100%	DIN 53504	Mpa	≥10
Tear strength	ISO 34-1	N/mm	≥120
Compression set (24 Hours @ 70°C / 20% deformation)	ISO 815-1	%	≤25
Compression set (24 Hours @ 100°C / 20% deformation)	ISO 815-1	%	≤40
Minimum service temperature		°C	-30
Maximum service temperature		°C	+115

Main Characteristics

- CFR 177.2600 FDA compliant
- 3-A compliant
- (EC) 1935/2004 & (EC) 10/2011 compliant
- Good resistance to the most common CIP fluids
- ADI free

Typical Products

- RTJ seals
- DIN 11851 D-Seals
- Static Seals & O-Rings
- Depositor seals
- Bespoke Parts

Please see the following page for FDA & (EC) 10/2011 migration results.

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Global migration results of FDA extraction on CIPU-VI95 material samples (mg/inch ²)				
FDA test method	Reflux test conditions	Mean over 3 samples	Limit*	Conclusion
CFR 177.2600	Deionised water, 7 hours	<1	20	PASS
CFR 177.2600	Deionised water, 2 hours	<1	1	PASS
CFR 177.2600	N-hexane, 7 hours	1	175	PASS
CFR 177.2600	N-hexane, 2 hours	<1	4	PASS

* Maximum acceptable global migration according to FDA CFR 177.1600

Global migration results of (EC) 10/2011 extraction on CIPU-VI95 material samples (mg/dm ²)				
Simulant	Reflux test conditions	Mean over 3 samples	Limit*	Conclusion
3% Acetic acid	2 hours @ 70°C	1	17	PASS
Isooctane	30 mins @ 40°C	1.6	22	PASS
95% Ethanol	2 hours @ 60°C	13.9	231	PASS

* Maximum acceptable global migration according to (EC) 10/2011

Changes in properties according to 3-A (18-03) Sanitary Class II test standards					
Test media	Test Parameter	Volume change %	Hardness change (Points)	Mass change %	Visual change
Hot air	168 Hrs @ 100°C	N/A	-2	N/A	No
Alkaline cleaner	22 Hrs @ 82°C	+1	-2	+2	No
Chlorine sanitizer solution	22 Hrs @ 23°C	+2	-3	+1	No
0.50% Nitric acid	22 Hrs @ 82°C	+2	-3	+2	No
Distilled water	22 Hrs @ 70°C	+1	-2	+1	No

The material shows migration results lower than those required by both FDA and (EC) 10/2011 standards and is suitable for repeated use in contact with aqueous foods and contact with fatty foods in accordance with the food simulants and reflux test conditions shown above.

Seals usually have a small contact area and a short exposure time (<1hr) with foodstuffs. Therefore, the overall migrations tests were performed appropriate the standardised test conditions OM3 (EU 10/2011 Annex V, table 3). That correspond to any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.

The calculation of the acceptable ratio of volume foodstuffs per seal surface is based on the verification of compliance by residual content per food contact surface area as indicated in EU 10/2011 Annex I and Annex V 2.1.8.

The migration tests according to ON EN 1186-3 and -14 respectively EU 10/2011 with the aforementioned simulant/s cover the groups of foodstuffs stated in EU 10/2011 Annex III table 2. To verify applicability with pure fats or oils and for foodstuffs with a fat reduction factors FRF < 2 it is recommended to carry out additional tests.

The results shown above only apply to the above conditions and samples tested, they may not apply to the form of finished parts, products and/or articles supplied that may be intended for food contact use. It is the customers responsibility to thoroughly qualify products in their specific application to determine performance, efficiency and safety for each end-use product. Any reliance on information provided by M Seals Ltd is therefore at the user's own risk. In no event will M Seals Ltd be liable for any loss, damage, claim or expense directly or indirectly arising or resulting from the use of parts supplied and/or any information or recommendations given.