



Declaration of Compliance

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:

This declaration is based on the results of the migration testing-and Compound research all reported and performed by **Intertek** Geleen Netherlands.

Copies of these reports are available upon request. **(3)**

Filcoflex TPU film Products to which this Declaration of Compliance applies **(1)**

- PU-UF03
- PU-UF05
- PU-UF07
- PU-UF09
- PU-UF1
- PU-UF15
- PU-UF20
- PU-UF30

The tests were performed on the material with and without welded seam.

Certifying the outcome of all testing to be for Sheet material and Finished product made by Filcoflex using the Filcoflex welding equipment and welding techniques.

Rules and Regulations to which were tested **(2)**

Regulation (EC) 1935/2004

Materials and Articles intended to come into contact with food

Filcoflex B.V. certifies that in the manufacture of our TPU films **(1)** our raw material supplier and film manufacturer use monomers & starting substances that comply with relevant requirements of Regulation (EC) 1935/2004)

Traceability of the product is ensured according to Regulation (EC) No. 1935/2004 through the SOP "Quality Certificate Manchettes PU-UF1 and PU-UF3". In this SOP a step-by-step procedure has been described from the receipt of the materials from the suppliers to the end materials delivered to the client.

COMMISSION REGULATION (EC) 2023/2006

Good manufacturing practices for items intended to come into contact with food.

Filcoflex B.V. certifies that in the manufacture of our TPU films **(1)** our raw material supplier and film manufacturer comply with relevant requirements in Commission Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come in contact with food.

Also a quality assurance program is in place. Each production step (cutting, welding, stitching, vacuum forming) will not lead to loss of quality and the end products will comply with the regulations included in this DoC.

REGULATION (EC) 10/2011

Plastic materials and articles intended to come into contact with food.

Filcoflex B.V. Netherlands certifies that in the manufacture of TPU films **(1)** our raw materials suppliers use monomers and starting substances that comply with relevant requirements of Regulation (EC) 10/2011 and amendments up to (EU) 2023/1627, including (EU 2020/1245)

The following substances subject to limitations and/or specifications and included in annex I and annex II have been used:

Name of substance	CAS no.	Ref. nr.	Limitations / Specification
Diphenylmethane-4,4"-diisocyanate	101-68-8	16630	SML = 0.01 mg/kg QM = 1 mg/kg
1,4-butanediol	110-63-4	13720/40580	SML = 5 mg/kg
Tetrahydrofuran	109-99-9	25150	SML = 0.6 mg/kg
PAA	-	-	SML = 0.01 mg/kg

This material does not contain intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC.

Migration tests of the above-mentioned product were performed and have shown that under these conditions of use migration limits were not exceeded. ***

- type of food intended to come in contact with material/article: Aqueous, acetic and alcoholic foodstuffs (up to 10% alcohol) and dry and fatty foodstuffs
- Shelf-life and material/article temperature: 0.5 hour at 70°C (migration tests for fatty foodstuffs performed in 95% ethanol during 0.5 hour at 40°C and in iso-octane during 4 hours at 60°C).
- Repeated use
- Possible treatment of material/article; no treatment
- Surface/volume ratio: 6 dm²/kg

***This statement does not apply to PU-UF20 and PU-UF30 for;

- PAA (not for sheet material, and not for the welded sheet material),
- THF only for sheet material, not for the welded sheet material

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REGULATION (EC) 1907/2006 (REACH)

Filcoflex B.V. Netherlands certifies that TPU films **(1)** contain no dangerous ingredients according to the REACH-Regulation (EC) No. 1907/2006.

FDA FOOD ADDITIVE REGULATION 21 CFR, 177.1680

Filcoflex B.V. Netherlands certifies that TPU films **(1)** are compliant to FDA 21 CFR 177.1680.

FDA 21 CFR 177.1680 lays down compositional requirements for polyurethane resins.

No end use tests have been laid down for polyurethane resins.

The composition of the material has been checked according to FDA 21 CFR 177.1680. Two of the three components are listed in this chapter. The third component is a solvent and will fall under the GMP. Based on the results of the residual content of tetrahydrofuran, it is shown that this component cannot migrate in higher concentration than 0.01 mg/kg food.

No end use tests are applicable for this chapter.

Chinese regulations

The supplier of this resin cannot state compliance towards GB 4806.6-2016 and GB 9685-2016.

The migration tests have been performed according to the applicable standard:

- GB 5009.156: National Food Safety Standard – General rules of the migration test pretreatment methods of food contact materials and articles.
- GB 31604.1 – 2015: National Food Safety Standard – General rules of migration test of food contact materials and articles
- GB 4806.7-2016: National Food Safety Standard – Food Contact Plastic Materials and Articles

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Simulants used for testing

Simulant A	10% Ethanol	Tested for repeated use
Simulant B	4% acetic acid	Tested for repeated use
Simulant D2	Vegetable Oil	Tried testing found technically not possible to test on Poly Urethane. A substitute simulant was tested instead **
**Simulant D2 substitute simulant; 95% ethanol and Iso-octane Tested for repeated use,		
Simulant E	MPPO Poly (2, 6-diphenyl-p-phenylene oxide)	Tested for repeated use

According to (EU) 10/2011, testing with 3% acetic acid, 10% ethanol and olive oil will cover contact with all types of foodstuffs.

According to GB 31604.1-2015, testing with 4% acetic acid, 10% ethanol and olive oil will cover contact with all types of foodstuffs, with an alcohol content of maximum 10%.

Since 4% acetic acid can be seen as the worst case for 3% acetic acid, the migration tests performed with 4% acetic acid, 10% ethanol and olive oil will cover both (EU) 10/2011 and GB 4806.7-2016 testing.

Simulant E is included in the testing to cover especially the dry foodstuffs.

Name of the Testing reports in which all testing results are listed: (3)

Migration Test Reports

- RE41844-02
- RE102491
- RE102491-001

A copy of the migration testing reports is available upon request

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Declaration free of specific Substances

Filcoflex hereby declares that none of the mentioned substances in below list **(4)** are intentionally added to any of the concerning the TPU film products **(1)** as well as the End products manufactured from said TPU film products

- Polyvinyl Chloride (PVC)
- Phthalates
- Animal derived raw materials
- BSE / TSE
- Bisphenol A
- Bisphenol B
- Silicone
- Latex
- Heavy Metals
 - o Mercury
 - o Cadmium
 - o Lead
 - o Hexavalent chromium

REACH – SVHC

Filcoflex hereby declares that the TPU film products **(1)** as well as the End Products manufactured from said TPU films do not contain any substances listed under the REACH - SVHC (ECHA updating list dated 2024.06.27)

This Declaration Applies to

This declaration applies to under listed orders, products, if not filled in this declaration is not valid.

Filcoflex Order Number: _____

Filcoflex Article Number(s): _____

Production Date: _____

Batch Number of Roll: _____

Order Number Customer: _____

Article Number Customer: _____

Declaration Template

To be filled and signed by Filcoflex

Template Declaration signed and Dated

Name: **Werner van Loon**
Function: Managing Director
Date : day-month-year



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