



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, NIAS study 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-UF07
- PU-UF1
- PU-UF15

Rules and Regulations to which was tested (2)

Regulation (EC) 1935/2004

Materials and Articles intended to come in to 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

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.

- 975/2009/EC - Amendments to directive 2002/72 EC
- 2002/72 EC - Repealed by this regulation

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 to maintain the quality and garrantue testing and certifications of the film products (1) and the end products manufactured of the films (1)

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.

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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.

Regulation GB 4806.7 – 2016

National Food safety Standard, food contact plastic materials and Articles

Filcoflex B.V. certifies that our TPU Films **(1)** have passed the tests according to (GB 4806.7 - 2016) and it's subsequent regulations;

- 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

Specific Migration has been performed relating to plastic materials and articles intended to come in to contact with food according to:

- GB 4806.6 – 2016
- GB 9685 – 2016

Simulants used for testing

Simulant A	10% Ethanol	Tested for repeated use
Simulant B	3% Acetic Acid	Tested for repeated use
Simulant C	20% Ethanol	not tested
Simulant D1	50% Ethanol	not tested
Simulant D2	Vegetable Oil	** Tried testing – found technically not possible to test on Poly Urethane. A substitute simulant was tested in stead
**Simulant D2 substitute simulant; ISO Octane		Tested for repeated use
Simulant E	MPPO Poly (2, 6-diphenyl-p-phenylene oxide)	Tested for repeated use

Food simulants A, B and C are designated for foodstuffs having a hydrophilic character, covering aqueous, acidic and alcoholic foods. and are able to extract hydrophilic substances.

The food simulant B is used for foodstuffs with a pH lower than 4.5 and the food simulant C is to be used for alcoholic beverages with a content of alcohol of less than or equal to 20% and for foodstuffs containing A significant amount of organic ingredients that make them more lipophilic.

Food simulants D1 and D2 are designated for foodstuffs having a lipophilic character. D1 simulant food is used for alcoholic beverages with an alcohol content of over 20% for dairy products and for emulsions of the oil type in water. The simulating D2 is used for food containing free fats in the surface.

The food simulant E is suitable for dried foods, but migration trials with this simulator will be mandatory from 2018.

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

- 001_PU-UF_03-07-1-15_Migration Testing Report_2020
Test Report – RE27963_Filcoflex

A copy of the migration testing report is available upon request

Declaration free of specific Substances

Filcoflex hereby declares that non 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 2020.01.16)

Name: Werner van Loon
Function: Managing Director
Date : 25-06-2020

