

## Safety declaration | Food contact compliance

### 1. Introduction

Filcoflex B.V. hereby declares that the products named in chapter 2, hereinafter referred to as the "products", meet the requirements according to the rules and regulations as listed in chapter 3, hereinafter referred to as the "rules and regulations". This means that the products are suitable for repetitive use in contact with foodstuff materials.

This declaration is based on the results of migration testing and compound research, of which are copies available upon request.

### 2. Products

This declaration applies to all end products manufactured by Filcoflex from casting resin materials with the following Filcoflex brand or type names;

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

The tests were performed on products with and without welded seam. Certifying the outcome of all testing to be for sheet material and end product using the Filcoflex B.V. welding equipment and welding techniques.

### 3. Rules and regulations

#### **Regulation (EC) 1935/2004**

Materials and articles intended to come into contact with food. Filcoflex B.V. certifies that in the manufacture of our products, our raw material supplier and film manufacturer use monomers and 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 products, 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. certifies that in the manufacture of our products, our raw

materials suppliers use monomers and starting substances that comply with relevant requirements of Regulation (EC) 10/2011 and amendments up to (EU) 2026/250.

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

| Name of Substance | CAS number   | Ref. number  | Limitations / Specifications                                |
|-------------------|--------------|--------------|-------------------------------------------------------------|
| Component A       | Confidential | Confidential | SML = 0.01 mg/kg<br>QM = 1 mg/kg                            |
| Component B       | Confidential | Confidential | SML = 5 mg/kg                                               |
| Component C       | Confidential | Confidential | SML = 0.6 mg/kg                                             |
| Component D       | Confidential | Confidential | SML (as sum) = 0.01 mg/kg<br>SML (individual) = 0.002 mg/kg |

This product 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 products were performed and have shown that under these conditions of use, migration limits were not exceeded.<sup>[1]</sup>

- ▶ Type of food intended to come in contact with the products: Aqueous, acetic and alcoholic foodstuffs (up to 10% alcohol) and dry and fatty foodstuffs
- ▶ Shelf-life and the products' 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 the products; no treatment
- ▶ Surface/Volume ratio: 6 dm<sup>2</sup>/kg

### **Regulation (EC) 1907/2006 (REACH)**

Filcoflex B.V. certifies that the products contain no dangerous ingredients according to the REACH-Regulation (EC) No. 1907/2006.

### **FDA Food additive regulation 21 CFR, 177.1680**

Filcoflex B.V. certifies that the products are compliant to FDA 21 CFR 177.1680.

FDA 21 CFR 177.1680 lays down compositional requirements for Poly Urethane resins.

No end use tests have been laid down for Poly Urethane resins.

The composition of the products have 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.

<sup>[1]</sup> This statement does not apply to PU-UF20 and PU-UF30 for; PAA (not for the sheet material, and not for the welded sheet material) and for Tetrahydrofuran only for the sheet material, not for the welded sheet material.

## Chinese regulations

The supplier of the products 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

## 4. 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<br>Found technically not possible to test on Poly Urethane. A substitute simulant was tested instead. <sup>[2]</sup> |
| <sup>[2]</sup> Alternative to simulant D2 | 95% Ethanol and Isooctane                   | Tested for repeated use                                                                                                            |
| Simulant E                                | MPPO Poly (2, 6-diphenyl-p-phenylene oxide) | Testes 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.

## 5. Name of testing reports

- ▶ RE41844-02
- ▶ RE102491
- ▶ RE102491-001

This Declaration Of Compliance can also be purchased with the Migration Testing Results.

A copy of the full laboratory migration testing reports can also be purchased.

For Both Please contact [certificates@filcoflex.com](mailto:certificates@filcoflex.com)

## 7. Declaration free of specific substances

Filcoflex B.V. hereby declares that none of the mentioned substances in below list are intentionally added to any of the products as well as the end products manufactured from the products.

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

## 8. REACH - SVHC

Filcoflex B.V. hereby declares that the products as well as the end Products manufactured from the products do not contain any substances listed under the REACH - SVHC (ECHA updating list dated 2025.01.21)

## 8. Product information

This declaration complies to under listed orders and products. If these details are not filled in, this safety declaration is not valid.

| Production date |  | Batch number |
|-----------------|--|--------------|
|                 |  |              |

  

| Filcoflex order number | Customer order number | End user order number |
|------------------------|-----------------------|-----------------------|
|                        |                       |                       |

  

| Filcoflex article number | Customer article number | End user article number |
|--------------------------|-------------------------|-------------------------|
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## Safety declaration signed and dated

**Name:** Werner van Loon

**Function:** Managing Director

**Date:**



### Disclaimer

The information contained herein is believed to be accurate as of the date of this document. If any of the above mentioned regulations change after the date of declaration, this information is no longer valid.

The manner in which you use our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products to determine suitability for your processing and intended use. Your analysis must at least include testing to determine suitability from a technical health, safety and environmental and regulatory standpoint.

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