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 roll and/or sheet materials with the following Filcoflex brand or type names;

- PU-UF3

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 (EC1935/2004)

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.

Included amendement regulations:

- Regulation (EC) 1882/2003
- Regulation (EC) 596/2009
- Regulation (EC) 2019/1381

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.

Included amendement regulations:
- Regulation (EC) 282/2008

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 profucts, 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	0.6
Component B	Confidential	Confidential	0.01
Component C	Confidential	Confidential	5
Component D	Confidential	Confidential	45
Component E	Confidential	Confidential	6
Component F	Confidential	Confidential	3
Component G	Confidential	Confidential	18

The composition of the material has been released to the testing laboratory under NDA.

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.
- 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^2/kg

Included amendement regulations:
- Regulation (EC) 321/2011
- Regulation (EC) 1282/2011
- Regulation (EC) 1183/2012
- Regulation (EC)202/2014
- Regulation (EC) 865/2014
- Regulation (EC) 2015/174
- Regulation (EC) 2016/1416
- Regulation (EC) 2017/752
- Regulation (EC) 2018/79
- Regulation (EC) 2018/213
- Regulation (EC) 2018/831
- Regulation (EC) 2018/213
- Regulation (EC) 2019/37
- Regulation (EC) 2019/1338
- Regulation (EC) 2020/1245
- Regulation (EC) 2023/1442
- Regulation (EC) 2024/245
- Regulation (EC) 2024/3190
- Regulation (EC) 2025/351
- Regulation (EC) 2025/1920
- Regulation (EC) 2026/245

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.

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 Found technically not possible to test on Poly Urethane. A substitie simulant was tested instead.[1]
[1]Alternative to simulant D2	95% Ethanol and Isooctane	Tested for repeated use
Simulant E	MPPO Poly (2, 6-diphenyl-p-phenyleme 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

- RE41844-01
- RE102491

This declaration is applicable for all the flexible end products manufactured from the products.

If you require more detailed information, the following documents can additionally be purchased. For more information or to purchase these documents, please contact certificates@filcoflex.com.

- 2.1 Supplier declaration | Filled in details of your end product
- 3.1 Material declaration | Detailed declaration for metal parts
- Migration testin report | A copy of the full laboratory test report

6. Summary of results

Overall migration tests for PU-UF3 (thickness 1mm)

Simulant	Test condition	Run 1 (mg/dm³)	Run 2 (mg/dm³)	Run 3 (mg/dm³)	Limit (mg/dm³)
10% Ethanol	2 hours at 90°C	1.0 1.0 1.0 **Mean: 1.0**	1.0 0.5 < 0.5 **Mean: 0.5**	0.5 1.0 1.0 **Mean: 1.0**	10
4% Acetic acid	2 hours at 90°C	0.5 1.0 0.5 **Mean: 0.5**	< 0.5 < 0.5 0.5 **Mean: 0.5**	< 0.5 < 0.5 1.0 **Mean: 0.5**	10
Olive oil	2 hours at 90°C	16.2 18.4 12.1 16.3 **Mean: 15.8**	3.5 3.6 2.6 5.0 **Mean: 3.7**	3.5 1.8 1.0 1.2 **Mean: 1.9**	10

Overall migration tests for PU-UF3 (thickness 1mm) with seams

Simulant	Test condition	Run 1 (mg/dm³)	Run 2 (mg/dm³)	Run 3 (mg/dm³)	Limit (mg/dm³)
10% Ethanol	2 hours at 90°C	2.0 1.0 0.5 **Mean: 1.0**	< 0.5 < 0.5 < 0.5 **Mean: < 0.5**	< 0.5 < 0.5 < 0.5 **Mean: < 0.5**	10
4% Acetic acid	2 hours at 90°C	< 0.5 1.5 < 0.5 **Mean: 1.0**	< 0.5 < 0.5 < 0.5 **Mean: < 0.5**	< 0.5 < 0.5 < 0.5 **Mean: < 0.5**	10
Olive oil	2 hours at 90°C	1.4 9.2 10.2 13.2 **Mean: 10.8**	9.2 8.4 6.6 5.7 **Mean: 7.5**	<1.0 <1.0 <1.0 <1.0 **Mean: <1.0**	10

Specific migration for PU-UF3 (thickness 1mm)

10% Ethanol, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	< 0.9 < 0.9 1.0 ± 0.1 **Mean: 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

4% Acetic Acid, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass
Arenic	0.01	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	Pass
Cadmium	0.002	< 0.0003 < 0.0003 < 0.0003 **Mean: < 0.0003**	< 0.0003 < 0.0003 < 0.0003 **Mean: < 0.0003**	< 0.0003 < 0.0003 < 0.0003 **Mean: < 0.0003**	Pass

Chromium	0.01	< 0.004 < 0.004 < 0.004 **Mean: < 0.004**	< 0.004 < 0.004 < 0.004 **Mean: < 0.004**	< 0.004 < 0.004 < 0.004 **Mean: < 0.004**	Pass
Lead	0.01	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	Pass
Mercury	0.01	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	Pass

Olive oil, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	Pass
Component E	6	3.2 ± 0.16 3.2 ± 0.16 2.6 ± 0.16 **Mean: < 3.0 ± 0.16**	< 1.6 < 1.6 < 1.6 **Mean: < 1.6**	< 1.6 < 1.6 < 1.6 **Mean: < 1.6**	Pass

95% Ethanol, 1.5 hours at 60°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	161.4 ± 18.5 184.3 ± 18.5 180.3 ± 18.5 **Mean: 175.3 ± 18.5**	76.7 ± 9.5 92.6 ± 9.5 79.3 ± 9.5 **Mean: 82.8 ± 9.5**	60.1 ± 6.0 48.2 ± 6.0 54.1 ± 6.0 **Mean: 54.1 ± 6.0**	Fail
Component D (With reduction factor =2)	45	**Mean: 87.65 ± 9.5**	**Mean: 41.4 ± 5.0**	**Mean: 27.05 ± 3.0**	Pass
Component F	3	5.0 ± 0.3 5.8 ± 0.3 5.7 ± 0.3 **Mean: 5.5 ± 0.3**	1.3 ± 0.07 1.4 ± 0.07 1.2 ± 0.07 **Mean: 1.3 ± 0.07**	6.0 ± 0.3 < 0.3 0.4 ± 0.3 **Mean: 0.4 ± 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

95% Ethanol, 1.5 hours at 40°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	49.3 ± 4.9 47.2 ± 4.9 48.8 ± 4.9 **Mean: 48.4 ± 4.9**	25.4 ± 2.5 22.6 ± 2.5 22.8 ± 2.5 **Mean: 23.6 ± 2.5**	22.0 ± 2.2 20.5 ± 2.2 22.3 ± 2.2 **Mean: 21.6 ± 2.2**	Pass

Iso-octane, 2 days at 60°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	< 6.0 < 6.0 < 6.0 **Mean: < 6.0**	< 6.0 < 6.0 < 6.0 **Mean: < 6.0**	< 6.0 < 6.0 < 6.0 **Mean: < 6.0**	Pass
Component F	3	8.2 ± 0.4 8.8 ± 0.4 8.6 ± 0.4 **Mean: 8.6 ± 0.4**	0.4 ± 0.02 0.4 ± 0.02 0.4 ± 0.02 **Mean: 0.4 ± 0.02**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

Tenax, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	Pass
Component C	5	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	1.3 ± 0.07 1.4 ± 0.07 1.3 ± 0.07 **Mean: 1.3 ± 0.07**	0.9 ± 0.05 0.9 ± 0.05 0.9 ± 0.05 **Mean: 0.9 ± 0.05**	< 0.1 0.7 ± 0.04 0.7 ± 0.04 **Mean: 0.5 ± 0.04**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

For Component B, the residual content in the sample has been determined. Based on the ratio between the mass and surface area of the sample and the standard EU ratio of 6 dm² surface area in contact with 1 kg of food, a worst-case calculation assuming 100% migration of the residual content has been performed.

Component	Restriction	Residual content (mg/kg material)	Ratio mass/ surface area (g/dm²)	Worst case calculation migration (mg/kg food)
Component B	SML = 0.01 mg/kg food QM = 1 mg/kg material	< 0.1 < 0.1 < 0.1 **Mean: < 0.1**	34.0	< 0.1 < 0.1 < 0.1 **Mean: < 0.1**

Specific migration for PU-UF3 (thickness 1mm) with seams

10% Ethanol, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	1.0 ± 0.1 1.0 ± 0.1 < 0.9 **Mean: 1.0 ± 0.1**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

4% Acetic Acid, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	1.0 ± 0.1 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	< 0.9 < 0.9 < 0.9 **Mean: < 0.9**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass
Arenic	0.01	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	< 0.002 < 0.002 < 0.002 **Mean: < 0.002**	Pass
Cadmium	0.002	< 0.0003 < 0.0003 0.0004 **Mean: 0.0003**	< 0.0003 < 0.0003 < 0.0003 **Mean: < 0.0003**	< 0.0003 < 0.0003 < 0.0003 **Mean: < 0.0003**	Pass

Chromium	0.01	< 0.004 < 0.004 < 0.004 **Mean: < 0.004**	0.008 < 0.004 < 0.004 **Mean: 0.005**	< 0.004 < 0.004 < 0.004 **Mean: < 0.004**	Pass
Lead	0.01	< 0.001 < 0.001 0.002 **Mean: 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	Pass
Mercury	0.01	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	< 0.001 < 0.001 < 0.001 **Mean: < 0.001**	Pass

Olive oil, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	< 0.2 < 0.2 < 0.2 **Mean: < 0.2**	Pass
Component C	5	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	< 2.0 < 2.0 < 2.0 **Mean: < 2.0**	Pass
Component E	6	4.9 ± 0.02 4.8 ± 0.02 4.3 ± 0.02 **Mean: 4.6 ± 0.02**	1.8 ± 0.01 2.1 ± 0.01 2.1 ± 0.01 **Mean: 2.1 ± 0.01**	1.6 ± 0.01 2.2 ± 0.01 < 1.6 **Mean: 1.8 ± 0.01**	Pass

95% Ethanol, 1.5 hours at 60°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	158.4 ± 16.0 153.2 ± 16.0 176.7 ± 16.0 **Mean: 162.7 ± 16.3**	78.7 ± 8.0 73.6 ± 8.0 82.2 ± 8.0 **Mean: 78.1 ± 8.0**	45.6 ± 5.0 65.5 ± 7.0 41.7 ± 5.0 **Mean: 54.1 ± 6.0**	Fail
Component D (With reduction factor =2)	45	**Mean: 81.35 ± 8.2**	**Mean: 39.05 ± 4.0**	**Mean: 25.45 ± 2.5**	Pass
Component F	3	5.6 ± 0.3 5.2 ± 0.3 5.7 ± 0.3 **Mean: 5.5 ± 0.3**	1.5 ± 0.1 1.5 ± 0.1 1.4 ± 0.1 **Mean: 1.5 ± 0.1**	0.6 ± 0.04 0.7 ± 0.04 < 0.3 **Mean: 0.5 ± 0.04**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

95% Ethanol, 1.5 hours at 40°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	49.3 ± 4.9 47.2 ± 4.9 48.8 ± 4.9 **Mean: 48.4 ± 4.9**	25.4 ± 2.5 22.6 ± 2.5 22.8 ± 2.5 **Mean: 23.6 ± 2.5**	22.0 ± 2.2 20.5 ± 2.2 22.3 ± 2.2 **Mean: 21.6 ± 2.2**	Pass

Iso-octane, 2 days at 60°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component D	45	< 6.2 < 6.2 < 6.2 **Mean: < 6.2**	< 6.2 < 6.2 < 6.2 **Mean: < 6.2**	< 6.2 < 6.2 < 6.2 **Mean: < 6.2**	Pass
Component F	3	8.7 ± 0.4 8.2 ± 0.4 8.9 ± 0.4 **Mean: 8.6 ± 0.4**	0.5 ± 0.02 0.4 ± 0.02 0.4 ± 0.02 **Mean: 0.4 ± 0.02**	< 0.3 < 0.3 < 0.3 **Mean: < 0.3**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

Tenax, 2 hours at 90°C

Component	SML (mg/kg)	Run 1 (mg/kg)	Run 2 (mg/kg)	Run 3 (mg/kg)	Conclusion
Component A	0.6	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	< 0.06 < 0.06 < 0.06 **Mean: < 0.06**	Pass
Component C	5	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	< 1.5 < 1.5 < 1.5 **Mean: < 1.5**	Pass
Component D	45	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	< 4.5 < 4.5 < 4.5 **Mean: < 4.5**	Pass
Component E	6	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	< 0.6 < 0.6 < 0.6 **Mean: < 0.6**	Pass
Component F	3	1.3 ± 0.07 1.2 ± 0.07 1.2 ± 0.07 **Mean: 1.3 ± 0.07**	0.9 ± 0.04 0.9 ± 0.04 0.9 ± 0.05 **Mean: 0.9 ± 0.04**	0.7 ± 0.03 0.7 ± 0.03 0.7 ± 0.03 **Mean: 0.7 ± 0.03**	Pass
Component G	18	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	< 1.8 < 1.8 < 1.8 **Mean: < 1.8**	Pass

For Component B, the residual content in the sample has been determined. Based on the ratio between the mass and surface area of the sample and the standard EU ratio of 6 dm² surface area in contact with 1 kg of food, a worst-case calculation assuming 100% migration of the residual content has been performed.

Component	Restriction	Residual content (mg/kg material)	Ratio mass/ surface area (g/dm²)	Worst case calculation migration (mg/kg food)
Component B	SML = 0.01 mg/kg food QM = 1 mg/kg material	< 0.1 < 0.1 < 0.1 **Mean: < 0.1**	34.0	< 0.1 < 0.1 < 0.1 **Mean: < 0.1**

Sensory tests

Sample	Median appearance	Median odor	Median taste	Median evaluation
PU-UF3 (thickness 1mm)	-	1.5	1.5 - 2.0	Passed
PU-UF3 with seams (thickness 1mm)	-	1 - 1.5	1.5	Passed

Tests according to GB 4806.7 for PU-UF3 (thickness 1mm)

Testes sample	Standard GB 4806.7-2016; National food safety standards for food contact plastic materials and products	Results
PU-UF3 (thickness 1mm)	Sensory index	Pass
	Potassium permanganate consumption determination	Pass
	Heavy metal (Pb)	Pass
	Decolorization test	Pass

Tests according to GB 4806.7 for PU-UF3 (thickness 1mm) with seam

Testes sample	Standard GB 4806.7-2016; National food safety standards for food contact plastic materials and products	Results
PU-UF3 (thickness 1mm) with seams	Sensory index	Pass
	Potassium permanganate consumption determination	Pass
	Heavy metal (Pb)	Pass
	Decolorization test	Pass

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

Please note that the list mentioned above, is only a part of the absent substances. For more specific lists, please refer to the following documents.

- Safety declaration - BSE/TSE & ADI
- Safety declaration - Leachable substances
- Safety declaration - Food allergens
- Safety declaration - PFAS

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)

Name:	Werner van Loon
Function:	Managing Director
Date:	27/10/2026



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.

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