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TEST REPORT – RE27963A_Filcoflex

MIGRATION TESTS ON PU MATERIAL

Requested by:

Filcoflex BV
Attn. Werner van Loon
Veerweg 19
5171 PW Kaatsheuvel
Netherlands



May 1, 2020



RE27963A_FILCOFLEX

May 1, 2020

**This version replaces all previous versions.
Reason for revision: including results for FDA.**

Dear Mr. van Loon,

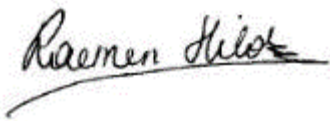
Hereby we present to you the results of the laboratory study, which was carried out by your request (SO27963).

The general conditions of delivery of Intertek Polychemlab B.V., located in Geleen, the Netherlands, are applicable. These conditions are an integral part of all research carried out and the services and consultations provided; where appropriate, expanded upon by agreements specific to the client. This report applies only to the sample(s) tested. If information about the measurement uncertainty of a method is required, this can be provided on request.

We trust that this information will meet your approval.

Yours sincerely,

Intertek Polychemlab B.V.



Hilde Raemen
Application Specialist Food Contact



Dr. Sander Jaeqx
Application Specialist Technique

RE27963A_FILCOFLEX

May 1, 2020

1 Introduction

Filcoflex has requested Intertek Polychemlab to perform migration testing on a PU material according to the European and Chinese regulations.

The following test conditions are requested:

- 0.5 hour at 90°C – repeated use
- 24 hours at 60°C – repeated use

The PU material will be in contact with all types of foodstuffs. As requested by Filcoflex, the material was also tested with MPPPO as simulant for dry foodstuffs.

The material that has been tested is PU-UF15 (1.5 mm thick).

Based on the thickness of the materials materials, PU-UF15 is the worst case sample and thus will also cover the following materials:

- PU-UF1 (1.0 mm thick)
- PU-UF07 (0.7 mm thick)
- PU-UF03 (0.3 mm thick)

The composition of the PU has been shared by the supplier.

2 Samples

The sample was received on October 21, 2019.

The registration of the sample (Intertek LIMS ID) can be found in table 1.

Table 1: Sample description

NO.	SAMPLE DESCRIPTION	INTERTEK LIMS ID
1	PU-UF15	22798566

3 Method(s) applied

Migration testing has been performed according to

- Commission Regulation (EU) 10/2011
- GB 4806.7 – 2016: National Food Safety Standard – Food Contact Plastic Materials and Articles.
- 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 for Migration Test of Food Contact Materials and Articles.

RE27963A_FILCOFLEX

May 1, 2020

3.1 Overall migration tests

Overall migration has been performed as described in Commission Regulation (EU) No. 10/2011 (including amendments) relating to plastic materials and articles intended to come in contact with food and GB 4806.7 – 2016: National Food Safety Standard – Food Contact Plastic Materials and Articles relating to plastic materials and articles intended to come in contact with food.

Test methods according to the parts of EN 1186 as listed below and where applicable updated by the provisions of the Regulation, which is more recent.

- EN 1186-1; Guide to the selection of conditions and test methods for overall migration.
- EN 1186-4; Test methods for overall migration into olive oil by cell.
- EN 1186-5; Test methods for overall migration into aqueous food simulants by cell.

The simulants and test conditions as listed in table 2 are chosen according to the rules as laid down in the Commission Regulation (EU) No. 10/2011 and GB 4806.7 – 2016: National Food Safety Standard – Food Contact Plastic Materials and Articles relating to plastic materials and articles intended to come in contact with food and based on the intended use.

Repeated use articles:

As the sample is intended for repeated use, overall migration tests have been carried out three times on a single sample, using a new portion of food simulant on each run. Overall migration was subsequently determined according to the standards listed above. The overall migration result in the second run should be lower than in the first run, and the result of the third run should be lower than in the second run. Compliance with the overall migration limit was verified based on the result from the third run.

Because it is not technically feasible to test the same sample three times when testing in olive oil, the overall migration test has been carried out by testing three different samples for three different durations - one, two and three times the applicable contact test time. The difference between the third and the second run results was considered to represent the overall migration. Compliance was verified on the basis of this difference, which should not exceed the overall migration limit. In addition, it should not be higher than the first run result and the difference between the second and the first run results.

Table 2: Simulants and test conditions overall migration

SIMULANTS	TEST CONDITIONS
4% acetic acid	0.5 hour at 90°C – repeated use 24 hours at 60°C – repeated use
10% ethanol	0.5 hour at 90°C – repeated use 24 hours at 60°C – repeated use
Olive oil	0.5 hour at 90°C – repeated use
95% ethanol*	30 minutes at 20°C – repeated use
Iso-octane*	24 hours at 30°C – repeated use

* Since it was technically not possible to test the sample in olive oil during 24 hours at 60°C, the substitute simulants were used instead. The test conditions of the substitute simulants have been chosen by Filcoflex.



RE27963A_FILCOFLEX

May 1, 2020

Tests in aqueous simulants have been performed in triplicate.

Tests in olive oil have been performed in fourfold.

3.2 Specific migration tests

3.2.1 Exposure to simulants

Specific migration has been performed in accordance with Commission Regulation (EU) No. 10/2011 (including amendments) relating to plastic materials and articles intended to come in contact with food and GB 4806.6-2016 and GB 9685-2016 and its supplementary announcements.

Exposure methods are according to EN 13130, where applicable updated by the provisions of the Regulation, which is more recent. Analytical methods are in-house methods.

Repeated use articles:

As the sample is intended for repeated use, specific migration tests have been carried out three times on a single sample, using a new portion of food simulant on each run.

Table 3: Simulants and test conditions specific migration

SIMULANTS	TEST CONDITIONS
10% ethanol	0.5 hour at 90 °C, repeated use 24 hours at 60 °C, repeated use
4% acetic acid	0.5 hour at 90 °C, repeated use 24 hours at 60 °C, repeated use
Olive oil	0.5 hour at 90 °C, repeated use 24 hours at 60 °C, repeated use
Iso-octane	12 hour at 60 °C, repeated use 24 hours at 60 °C, repeated use
MPPO	0.5 hour at 90 °C, repeated use 24 hours at 60 °C, repeated use

Exposures have been performed in triplicate.

3.2.2 Analysis of specific migration components

The components listed in table 4 are subject to a specific migration limit (SML) set out in the Union list of Commission Regulation (EU) No. 10/2011 and GB 9685-2016 and its supplementary announcements.

This list is based on information provided by the client or its suppliers. Intertek cannot be held responsible for incorrect or incomplete information.

The specific migration limit should comply in the third run. However for components that are prohibited from migrating or from being released in detectable quantities (< 0.01 mg/kg), the specific migration should already comply in the first run.

RE27963A_FILCOFLEX

May 1, 2020

Table 4: Specific migration components to be tested

COMPONENT	CAS	SML (mg/kg food)	SIMULANTS	METHOD
Diphenylmethane-4,4''-diisocyanate	101-68-8	0.01 QM = 1	material	LC-MS/MS
1,4-butanediol	110-63-4	5	10% ethanol 4% acetic acid Olive oil MPPO	GC-FID
Tetrahydrofuran	109-99-9	0.6	10% ethanol 4% acetic acid Olive oil MPPO	GC-FID
PAA	-	0.01	10% ethanol 4% acetic acid Iso-octane	Spectrophotometric
Tetrahydrofuran	109-99-9	0.01	material	GC-MS

3.3 GB 4806.7-2016 test

Additional 4806.7 GB testing are performed by Intertek China, including:

- KMnO_4
- Heavy metal (as Pb)
- Decolorization test
- Sensory requirements

3.4 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.

RE27963A_FILCOFLEX

May 1, 2020

4 Results

4.1 Overall migration tests

Contact area aqueous simulants:	0.8 dm ²
Volume aqueous simulants:	100 ml
Contact area olive oil:	0.8 dm ²
Mass Olive oil:	90 g
Start date migration:	October 24, 2019

The overall migration test results in aqueous simulants are presented in table 5 and 6 and are expressed in mg/dm².

For aqueous simulants, compliance with the overall migration limit should be verified on the basis of the level of the overall migration found in the third test. The first test is included to check if migration does not increase with subsequent tests.

Table 5: Overall migration results in aqueous PU-UF15, 0.5 hour at 90°C

REPLICATES	10% ETHANOL 0.5 HOUR AT 90°C RUN 1 (mg/dm ²)	10% ETHANOL 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)	4% ACETIC ACID 0.5 HOUR AT 90°C RUN 1 (mg/dm ²)	4% ACETIC ACID 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)
1	< 0.5	< 0.5	0.6	< 0.5
2	0.5	< 0.5	< 0.5	< 0.5
3	< 0.5	< 0.5	< 0.5	< 0.5
MEAN RESULT	0.5	< 0.5	0.5	< 0.5

Table 6: Overall migration results in aqueous simulants PU-UF15, 24 hour at 60°C

REPLICATES	10% ETHANOL 24 HOURS AT 60°C RUN 1 (mg/dm ²)	10% ETHANOL 24 HOURS AT 60°C RUN 3 (mg/dm ²)	4% ACETIC ACID 24 HOURS AT 60°C RUN 1 (mg/dm ²)	4% ACETIC ACID 24 HOURS AT 60°C RUN 3 (mg/dm ²)
1	< 0.5	< 0.5	< 0.5	< 0.5
2	< 0.5	< 0.5	< 0.5	0.5
3	< 0.5	< 0.5	< 0.5	0.6
MEAN RESULT	< 0.5	< 0.5	< 0.5	0.5

The overall migration test results in olive oil are presented in table 7 and 8 and are expressed in mg/dm².

For olive oil, the difference between the third and the second test results should be considered to represent the overall migration. Compliance should be verified on the basis of this difference, which should not exceed the overall migration limit. In addition, it should not be higher than the first result and the difference between the second and the first test results.

RE27963A_FILCOFLEX

May 1, 2020

Table 7: Overall migration results in olive oil PU-UF15, 0.5 hour at 90°C

REPLICATES	OLIVE OIL 0.5 HOUR AT 90°C RUN 1 (mg/dm ²)	OLIVE OIL 0.5 HOUR AT 90°C RUN 3 – RUN 2 (mg/dm ²)
1	< 3.0	< 3.0
2	< 3.0	< 3.0
3	< 3.0	< 3.0
4	< 3.0	< 3.0
MEAN RESULT	< 3.0	< 3.0

Table 8: Overall migration results PU-UF15; 95% ethanol and iso-octane

REPLICATES	95% ETHANOL 0.5 HOUR AT 20°C RUN 1 (mg/dm ²)	95% ETHANOL 0.5 HOUR AT 20°C RUN 3 (mg/dm ²)	ISO-OCTANE 24 HOURS AT 30°C RUN 1 (mg/dm ²)	ISO-OCTANE 24 HOURS AT 30°C RUN 3 (mg/dm ²)
1	4.0	1.1	4.3	1.8
2	3.7	1.0	4.5	1.7
3	3.8	1.4	4.0	2.0
MEAN RESULT	3.8	1.2	4.3	1.9

4.2 Specific migration tests

Contact area:	0.8 dm ²
Volume aqueous simulants:	100 ml
Mass Olive oil:	90 g
Start date migration:	24-10-2019
Analysis period:	Week 43 - 47

The specific migration test results are mentioned in table 9 to 12 and are expressed in mg/kg foodstuff, based on the conventional EU food contact ratio of 1 kg of food in contact with 6 dm² of surface area.

Results of the third exposure run are reported, except where indicated otherwise, as for components that are prohibited from migrating or from being released in detectable quantities, results should comply in the first run and are reported as such.

RE27963A_FILCOFLEX

May 1, 2020

Table 9: Specific migration results PU-UF15; 0.5 hour at 90 °C (12 hours at 60 °C for iso-octane)

COMPONENT	SML (mg/kg)	10% ETHANOL 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)	4% ACETIC ACID 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)	OLIVE OIL 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)	MPPO 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)
1,4-butanediol	5	< 1.5 < 1.5 < 1.5 Mean: < 1.5	< 1.5 < 1.5 < 1.5 Mean: < 1.5	< 3 < 3 < 3 Mean: < 3	< 1.5 < 1.5 < 1.5 Mean: < 1.5
Tetrahydrofuran	0.6	< 0.2 < 0.2 < 0.2 Mean: < 0.2	< 0.2 < 0.2 < 0.2 Mean: < 0.2	0.4 0.4 0.4 Mean: < 0.4	< 0.06 < 0.06 < 0.06 Mean: < 0.06

Table 10: Specific migration results PU-UF15; 24 hour at 60 °C

COMPONENT	SML (mg/kg)	10% ETHANOL 24 HOURS AT 60°C RUN 3 (mg/dm ²)	4% ACETIC ACID 24 HOURS AT 60°C RUN 3 (mg/dm ²)	OLIVE OIL 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)	MPPO 0.5 HOUR AT 90°C RUN 3 (mg/dm ²)
1,4-butanediol	5	< 1.5 < 1.5 < 1.5 Mean: < 1.5	< 1.5 < 1.5 < 1.5 Mean: < 1.5	< 3 < 3 < 3 Mean: < 3	< 1.5 < 1.5 < 1.5 Mean: < 1.5
Tetrahydrofuran	0.6	< 0.2 < 0.2 < 0.2 Mean: < 0.2	< 0.2 < 0.2 < 0.2 Mean: < 0.2	0.4 0.4 0.4 Mean: < 0.4	< 0.06 < 0.06 < 0.06 Mean: < 0.06

Table 11: Specific migration results PU-UF15; 0.5 hour at 90 °C (12 hours at 60 °C for iso-octane)

COMPONENT	SML (mg/kg)	10% ETHANOL 0.5 HOUR AT 90°C (mg/dm ²) RUN 1	4% ACETIC ACID 0.5 HOUR AT 90°C (mg/dm ²) RUN 1	ISO-OCTANE 12 HOURS AT 60°C (mg/dm ²) RUN 1
PAA	0.01	< 0.01 < 0.01 < 0.01 Mean: < 0.01	< 0.01 < 0.01 < 0.01 Mean: < 0.01	< 0.01 < 0.01 < 0.01 Mean: < 0.01

RE27963A_FILCOFLEX

May 1, 2020

Table 12: Specific migration results PU-UF15; 24 hour at 60 °C

COMPONENT	SML (mg/kg)	10% ETHANOL 24 HOUR AT 60°C (mg/dm ²) RUN 1	4% ACETIC ACID 24 HOUR AT 60°C (mg/dm ²) RUN 1	ISO-OCTANE 24 HOURS AT 60°C (mg/dm ²) RUN 1
PAA	0.01	< 0.01 < 0.01 < 0.01 Mean: < 0.01	(1)	< 0.01 < 0.01 < 0.01 Mean: < 0.01

(1) No specific migration value can be given. For the spectrophotometrical method a result lower than 0.002 mg/6 dm² must be obtained to be sure the specific migration of primary aromatic amines expressed as aniline is lower than 0.01 mg/kg. The result was higher than 0.002 mg/6 dm². So no conclusion can be drawn for the specific migration of the primary aromatic amines. A follow-up test using an LC MS-MS should be performed to verify compliance

For diphenylmethane-4,4''-diisocyanate and tetrahydrofuran, 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.

The results of the residual content analysis are expressed in mg/kg finished article and the results of the worst case calculations are expressed in mg/kg food, both mentioned in table 13.

Table13: Residual content and worst case migration calculation PU-UF15

COMPONENT	RESTRICTION	RESIDUAL CONTENT (mg/kg material)	RATIO MASS/SURFACE AREA (g/dm ²)	WORST CASE CALCULATION MIGRATION (mg/kg food)
Diphenylmethane-4,4''-diisocyanate	SML = 0.01 QM = 1	< 0.1 < 0.1 < 0.1 Mean: < 0.1	8.6	< 0.01 < 0.01 < 0.01 Mean: < 0.01
Tetrahydrofuran	0.01	0.086 0.104 0.051 Mean: 0.080	8.6	0.004 0.005 0.003 Mean: 0.004

RE27963A_FILCOFLEX

May 1, 2020

4.3 GB 4806.7-2016 test

A summary of the results of the 4806.7 GB testing are mentioned in table 9. The full report SHAH01157265 can be found in Appendix I.

Table 9: Summary results 4806.7 GB testing on Sample PU-UF15

TESTED SAMPLE	STANDARD	RESULTS
PU-UF15	GB 4806-7-2016; <i>National food safety standards for food contact plastic materials and products</i>	
	<ul style="list-style-type: none"> Sensory index 	PASS
	<ul style="list-style-type: none"> Potassium Permanganate consumption determination 	PASS
	<ul style="list-style-type: none"> Heavy metal (Pb) 	PASS

4.4 FDA 21 CFR 177.1680

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.

5 Conclusions

5.1 Overall migration tests

5.1.1 PU-UF15

The overall migration results obtained from the PU-UF15 were found to be in compliance with the overall migration limit (10 mg/dm²) as defined in Commission Regulation (EU) No. 10/2011 (including amendments) for food contact materials and GB 4806.7 – 2016: National Food Safety Standard – Food Contact Plastic Materials and Articles relating to plastic materials and articles intended to come in contact with food for the tests with 10% ethanol, 4% acetic acid, olive oil, 95% ethanol and iso-octane under the above mentioned test conditions.

RE27963A_FILCOFLEX

May 1, 2020

5.2 Specific migration tests

5.2.1 PU-UF15

The specific migration results obtained 1,4-butanediol and tetrahydrofuran from PU-UF15 were found to be in compliance with their respective specific migration limits as defined in Commission Regulation (EU) No. 10/2011 (including amendments) for food contact materials and GB 4806.6-2016 and GB 9685-2016 and its supplementary announcements, for the tests with 10% ethanol, 4% acetic acid, olive oil, MPPO under the above mentioned test conditions and for the test as residual content directly on the material.

The specific migration results obtained for primary aromatic amines from PU-UF15 were found to be in compliance with their respective specific migration limits as defined in Commission Regulation (EU) No. 10/2011 (including amendments) for food contact materials and GB 4806.6-2016 and GB 9685-2016 and its supplementary announcements, for the tests with 10% ethanol and iso-octane under the above mentioned test conditions.

The specific migration results obtained for primary aromatic amines from PU-UF15 were found to be in compliance with their respective specific migration limits as defined in Commission Regulation (EU) No. 10/2011 (including amendments) for food contact materials and GB 4806.6-2016 and GB 9685-2016 and its supplementary announcements, for the tests with 4% acetic acid with the test condition 0.5 hours at 90 °C.

The specific migration results obtained for primary aromatic amines from PU-UF15 were found not to be in compliance with their respective specific migration limits as defined in Commission Regulation (EU) No. 10/2011 (including amendments) for food contact materials and GB 4806.6-2016 and GB 9685-2016 and its supplementary announcements, for the tests with 4% acetic acid with the test condition 24 hours at 60°C.

5.3 GB 4806.7-2016 test

The sample PU-UF15 passes the requirements as laid down in the GB 4806.7-2016 for the tests as performed under the conditions as mentioned in the test report (Appendix I).

5.4 FDA 21 CFR 177.1680

The sample PU-UF15 is compliant with FDA 21 CFR 177.1680.



RE27963A_FILCOFLEX

May 1, 2020

Appendix I: Report SHAH01157265



Test Report

Number: SHAH01157265

Applicant: INTERTEK POLYCHEMLAB B.V
KOOLWATERSTOFSTRAAT 2
Attn: HILDE RAEMEN

Date: Nov 01, 2019

Sample Description:

One (1) submitted sample said to be:

Item Name : (1) PU-UF15

Tests Conducted:

As requested by the applicant, for details refer to attached page(s).

To be continued.

Authorized By:
For Intertek Testing Services Ltd., Shanghai

Bill Zhang
General Manager



Page 1 of 3

Intertek Testing Services Ltd., Shanghai
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This version replaces all previous versions.



RE27963A_FILCOFLEX

May 1, 2020



Test Report

Number: SHAH01157265

Tests Conducted

Food contact materials and products

As per GB 4806.7-2016 "National food safety standards for food contact plastic materials and products".

I. Sensory Index

Appearance of sample: Normal color, odorless, no impurity.

Soaking liquid of sample: No turbidity, no precipitation, odorless, and no other sensory deterioration.

II. Physicochemical Index

1 Potassium Permanganate consumption determination
(Testing method: GB31604.2-2016)

(1) Test condition

Time and Temperature (Distilled water)
2 hours at 60 °C

(2) Tested Result

Tested component	Result (mg/kg)	Limit (mg/kg)
(1)	1.3	10

2 Heavy metal (Pb) (4% (v/v) Acetic acid, 60°C, 2 hours)
(Testing method: GB31604.9-2016)

Tested component	Result (mg/kg)	Limit (mg/kg)
(1)	<1	1

Remark: As per client's request, the above condition and food simulant was / were used for the test.

Detection limit: Potassium Permanganate consumption determination 1.0 mg/kg
Heavy metal (Pb) 1 mg/kg

Conclusion:

Tested Sample	Standard	Result
Tested component of submitted sample	GB 4806.7-2016 "National food safety standards for food contact plastic materials and products"	
	- Sensory Index	PASS
	- Potassium Permanganate consumption determination	PASS
	- Heavy metal (Pb)	PASS

Remark: The testing results are only valid for the sample tested. Without consent of the testing organization, the clients shall not be unauthorized use of test result for improper propaganda.

Tested Component:

PU-UF15

Date sample received: Oct 25, 2019

Testing Period: Oct 25, 2019 to Nov 01, 2019

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To be continued.



RE27963A_FILCOFLEX

May 1, 2020



Test Report

Number: SHAH01157265

Tests Conducted



End of report.

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