



CHEMISCHES LABOR
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SACHVERSTÄNDIGEN GMBH

Analytik, Gutachten, Beratung

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Report




Date: 01.10.2018

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Test Report No.: PB1807258 F
Order Date: 11 June 2018
Order issued: by client
Test order: Migration analysis according to Reg. (EU) 10/2011
Plastic goods with repeated food contact
Sample number: **318012686-01**
Test item: UHMW-PE Folien / Platten
Identification: UHMW-PE PG 5415 natur, PG 5415 BF schwarz
Sample amount: ca. 6 x 50 cm²
Sampling: by client
Delivery date: 11 June 2018 by parcel service

Responsible for the report


state certified Food Chemist Stefan Witte
Head of Food Analysis



TEST RESULTS

Test period: 11.06.2018 - 20.09.2018

color fastness test

Test with perspiration simulant (ASU 82.02-13) : 5
(complete color fastness)

Overall migration _a

Regulation (EU) 10/2011 and 2016/1416 / Guideline 82/711/EWG

ASU B 80.30-1 (EC) – Basic rules for determining overall migration

ASU B 80.30-2 (EC) – List of solvents for simulation

ASU B 80.30-3 (EC) – Additional requirements

ASU B 80.30-4 (EC) – Guideline for selection of test conditions *and*

National annexes ASU B 80.30-5 (EC) – ASU B 80.30-19 (EC)

OM 1: Any food contact at frozen and refrigerated conditions.

OM 2: Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

OM 3: Any contact conditions that include heating up to 70 °C for up to 2 hours or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.

OM 4: High temperature applications for all food simulants at temperature up to 100 °C.

OM 5: High temperature applications up to 121 °C.

OM 7: High temperature applications with fatty foods exceeding the conditions of OM5. Test OM 7 covers also food contact conditions described for OM1, OM2, OM3 and OM4.

Solvent for simulation : Ethanol 10 Vol.-%

Contact conditions : 2 h reflux / OM 5

Remarks : immersion

		1	2	3	Average	Limit
Overall migration	mg/dm ²	<2	<2	<2	<2	10
2. Test	mg/dm ²		not necessary			
3. Test	mg/dm ²		not necessary			

Solvent for simulation : Acetic acid 3 %ig

Contact conditions : 2 h reflux / OM 5

Remarks : immersion

		1	2	3	Average	Limit
Overall migration	mg/dm ²	<2	<2	<2	<2	10
2. Test	mg/dm ²		not necessary			
3. Test	mg/dm ²		not necessary			

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Solvent for simulation : Vegetable oil
Contact conditions : 2 h 175 °C / OM 7
Remarks : Sample deforms, migration test with oil not possible

		1	2	3	Average	Limit
Overall migration	mg/dm ²	-	-	-	-	-

Solvent for simulation : Ethanol 95 Vol.-% (Replacement test for vegetable oil)
Contact conditions : 6 h 60 °C / Replacement test for OM 7 with vegetable oil (2 h 175 °C)
Remarks : immersion

		1	2	3	Average	Limit
Overall migration	mg/dm ²	<2	<2	<2	<2	10
2. Test	mg/dm ²		not necessary			
3. Test	mg/dm ²		not necessary			

Solvent for simulation : Isooctane (Replacement test for vegetable oil)
Contact conditions : 4 h 60 °C / Replacement test for OM 7 with vegetable oil (2 h 175 °C)
Remarks : immersion

		1	2	3	Average	Limit
Overall migration	mg/dm ²	2,7	3,0	2,8	2,8	10
2. Test	mg/dm ²		not necessary			
3. Test	mg/dm ²		not necessary			

Overall migration according to FDA/CFR

Solvent for simulation : n-hexane (Test according to FDA §177.1520 CFR Title 21 Ch. I)
Contact conditions : 2 h 50 °C
Remarks : immersion

		1	2	3	Average	Limit
Overall migration	%	<0,1	<0,1	<0,1	<0,1	5,5

Solvent for simulation : Xylene (Test according to FDA §177.1520 CFR Title 21 Ch. I)
Contact conditions : 2 h 25 °C
Remarks : immersion

		1	2	3	Average	Limit
Overall migration	%	<0,1	<0,1	<0,1	<0,1	11,3

Explanations:

a = accredited method | f=External investigation in accredited laboratory | u = subcontracted | < = below limit of quantification

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Evaluation

The present sample complies within the scope of analysis the requirements of

- (1) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (ABl. No L 338/4), last changed by Reg. (EC) No. 596/2009 of 18 June 2009 (ABl. No L 188/14),
- (2) German food law „Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB)“ revised version of 3 June 2013, last changed by Art. 1 of „Gesetzes zur Änderung futtermittelrechtlicher und tierschutzrechtlicher Vorschriften“ of 30.06.2017 (BGBl. I No. 44, S. 2147),
- (3) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, last changed by Reg. (EU) 2018/79 of 18 January 2018 (ABl. No L 14/31) und Reg. (EU) 2018/213 of 12 February 2018 (ABl. No. L 41/6),
- (4) the Code of Federal Regulations (CFR), Food and Drug Administration (FDA), Title 21 Chapter I § 177.1520 (Edition 4-1-11).

The present sample is suitable for direct and repeated contact with food according to the migration tests. This includes long-term storage at room temperature and high-temperature applications up to 121 °C.

This evaluation remains valid as long as the raw materials, the technological manufacturing process and the applicable legislation keep unchanged.