Test report ID 7748 v.2

Customer

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Assignment

Measurlabs provided testing services for food contact material as requested by the customer.

Sample(s)

Sampling was performed by the customer.

Description: water softener device
Date of reception (dd/mm/yyy): 27/10/2023 (dd/mm/yyyy)
Batch number or other sample identification: model S550
Materials: multi-material instrument
Note: the sample unit was provided without the ion-exchange resin.

Results

The results presented on the next page(s) relate to the tested sample(s) only.

Note

Additional results provided on 02 January 2024.

Summary of the results

Tests performed	Compliance
Overall migration testing – simulant A (water), repeated use	Compliant[1]
Sensory analysis – transfer of odor and flavor from food contact materials	Compliant[1]
Specific migration testing – elements of Annex II in Commission Regulation (EU) No 10/2011	Compliant[1,2]
Specific migration of mineral oil (MOSH/POSH and MOAH)	See results
Specific migration testing – primary aromatic amines (PAA)	Compliant[1,2]
Release of N-nitrosamines	Compliant[2]
Specific migration testing – formaldehyde	Compliant[1,2]
Specific migration testing – vinyl chloride	Compliant[1]
Specific migration testing – non-intentionally added substances (NIAS), GC Orbitrap	Compliant[3]
Specific migration testing – non-intentionally added substances (NIAS), LC Orbitrap	Compliant[3]

[1] Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023).
[2] BfR recommendation XXI/1 as of 01.02.2023
[3] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, as amended

On Thursday, 21 December 2023, issued by (amended on 02 January 2024)

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Test plan for evaluation of compliance for food contact

Description

Based on the documentation provided by the manufacturer, the test plan presented in **Table 1** was prepared to evaluate migration of substances restricted by regulations or recommendations in the European Union for materials intended for food contact. The complete instrument was tested to simulate migration under real-use conditions.

The preparation of the test simulant was performed using German Environment Agency guidelines for materials intended for contact with drinking water; please details on **Page 6.**

Table 1. Test plan of the water softener S550 instrument based the materials present in the instrument that have a significant wetted surface.
Note: the outlet water of the complete instrument (without an ion-exchange resin) was tested rather than each part individually.

Resin	POM	EPDM	Glassfiber PP / PP	PVC	Polyester	Lubricants, adhesives
Material type	**Plastic**	**Rubber**	**Plastic**	**Plastic**	**Plastic**	-
Regulatory reference	*	**	*	*	*	
Overall migration: simulant A (water), repeated use	x	x	x	x	x	
Sensory analysis: transfer of odor and flavor from food contact materials	x	x	x	x	x	x
Specific migration: elements of Annex II in Commission Regulation (EU) No 10/2011	x	Zn, Pb, Al	x	x	x	
Specific migration: mineral oil (MOSH/POSH and MOAH)						x
Specific migration: primary aromatic amines	x	x	x	x	x	x
Release of N-nitrosamines		x				
Specific migration: formaldehyde	x	x				x
Specific migration: vinyl chloride				x		
Specific migration: non-intentionally added substances, GC-MS	x	x	x	x	x	x
Specific migration: non-intentionally added substances, LC-MS	x	x	x	x	x	x

* Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023).
** BfR recommendation XXI/1 as of 01.02.2023

The sampling protocol was adapted from *German Environment Agency document Evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL): General part chapter 6.3 Table 5.* The compliance of the results was evaluated here by treating concentration per liter of outlet water as the same as migration into a kilogram of food.

The sampling was done as described below.

The water temperature should be at 23 ± 2 °C.

Step 1. The instrument was attached to a water inlet. The inlet water was used as a control for the analysis.
Step 2. The instrument was flushed for 20 min.
Step 3. The water flow was halted and the water was left inside the instrument for 24 ± 0.5 h.
Step 4. After 24 h, the water flow was opened and 8 liters of water was collected and discarded.
Step 5. The water was left inside the instrument for 72 ± 0.5 h.
Step 6. After 72 h, 8 liters of outlet water was collected from the instrument; this was the **1st migration.**
Step 7. The water was left inside the instrument for 72 ± 0.5 h.
Step 8. After 72 h, 8 liters of outlet water was collected from the instrument; this was the **2nd migration.**
Step 9. The water was left inside the instrument for 72 ± 0.5 h.
Step 10. After 72 h, 8 liters of outlet water was collected from the instrument; this was the **3rd migration.**

Table 2. Analysis performed per each migrate

Analysis	1st migration	2nd migration	3rd migration
Overall migration: simulant A (water), repeated use	x	x	x
Sensory analysis (color, taste, odor, turbidity)	x		
Specific migration of elements in Annex II of EU No 10/2011	x		
Specific migration of MOSH/POSH and MOAH	x		
Specific migration of primary aromatic amines	x		
Specific migration of N-nitrosamines	x		
Specific migration of formaldehyde	x		
Specific migration of vinyl chloride	x		
Specific migration of NIAS (GC-MS)	x		
Specific migration of NIAS (LC-MS)	x		

Test results - organoleptic properties

Test methods Sensory analysis with in-house method. Test performed by an ISO/IEC 17025 accredited external service provider.

Test parameter	Simulant	Conditions	Value[1]	Criteria	Compliance[1]
Color, odor, flavor, turbidity	See Page 4	See Page 4	No deviation compared to control detected	No deteriorating effect detected	compliant

[1] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, Art. 3

Test results - overall migration, repeated use

Test methods	Test methods according to EN 1186-1. For migration method and for preparation of the simulant, please see Page 4. Test performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	**Simulant A (water)**: For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable

Test - simulant	Simulant	Unit[1]	1st migration	2nd migration	3rd migration	Criteria[2]	Compliance[3]
Overall migration - simulant A	water	mg/kg	40	58	Not detected	≤ 60	compliant[4]

[1] The result is for mg of residue after evaporation per liter of water.

[2] Result may not increase upon subsequent migrations. Compliance is evaluated based on the 3rd migration.

[3] Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023)

[4] The overall migration result was acquired by subtracting the content of residue after evaporation in a blank sample (i.e. tapwater; result 481 mg/kg) from the result of the water that had passed the instrument. However, as the method has not been validated for tapwater, value for LoD or LoQ cannot be indicated. Regardless, the compliance for overall migration as defined in Regulation (EU) No 10/2011 for repeated use articles was shown.

Test results - specific migration of primary aromatic amines

Test methods	In-house method RU-MET-413, UPLC-MS/MS. For migration method and for preparation of the simulant, please see Page 4. The test was performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable

Parameter / substance	CAS number	Unit[1]	Result	Criteria	Compliance[2,3]
2-Amino-4-nitrotoluene	99-55-8	mg/kg	< 0.001	≤ 0.002	compliant
2-Naphthylamine	91-59-8	mg/kg	< 0.001	≤ 0.002	compliant
2,4-Diaminoanisole	615-05-4	mg/kg	< 0.001	≤ 0.002	compliant
2,4-Toluenediamine	95-80-7	mg/kg	< 0.001	≤ 0.002	compliant
2,4,5-Trimethylaniline	137-17-7	mg/kg	< 0.001	≤ 0.002	compliant
3,3'-Dichlorobenzidine	91-94-1	mg/kg	< 0.001	≤ 0.002	compliant
3,3'-Dimethoxybenzidine	119-90-4	mg/kg	< 0.001	≤ 0.002	compliant
4,4'-Diamino-3,3'-dimethyldiphenylmethane,	838-88-0	mg/kg	< 0.001	≤ 0.002	compliant
3,3'-Dimethylbenzidine	119-93-7	mg/kg	< 0.001	≤ 0.002	compliant
4-Aminoazobenzene	60-09-3	mg/kg	< 0.001	≤ 0.002	compliant
4-Aminodifenyl	92-67-1	mg/kg	< 0.001	≤ 0.002	compliant
4-Chloro-o-toluidine	95-69-2	mg/kg	< 0.001	≤ 0.002	compliant
4,4'-Diaminodiphenylmethane	101-77-9	mg/kg	< 0.001	≤ 0.002	compliant
4,4'-Methylene-bis(2-chloroaniline)	101-14-4	mg/kg	< 0.001	≤ 0.002	compliant
4,4'-Oxydianiline	101-80-4	mg/kg	< 0.001	≤ 0.002	compliant
4,4'-Thiodianiline	139-65-1	mg/kg	< 0.001	≤ 0.002	compliant
Benzidine	92-87-5	mg/kg	< 0.001	≤ 0.002	compliant
o-Aminoazotoluene	97-56-3	mg/kg	< 0.001	≤ 0.002	compliant
o-Anisidine	90-04-0	mg/kg	< 0.001	≤ 0.002	compliant
o-Toluidine	95-53-4	mg/kg	< 0.001	≤ 0.002	compliant
p-Chloroaniline	106-47-8	mg/kg	< 0.001	≤ 0.002	compliant
p-Cresidine	120-71-8	mg/kg	< 0.001	≤ 0.002	compliant
2,4-Dimethylaniline	95-68-1	mg/kg	< 0.001	-	-
2,6-Dimethylaniline	87-62-7	mg/kg	< 0.001	-	-
2,6-Toluenediamine	823-40-5	mg/kg	< 0.001	-	-
Aniline	62-53-3	mg/kg	< 0.001	-	-
Sum of primary aromatic amines	-	mg/kg	< 0.001	≤ 0.01	compliant

[1] The result is for mg of substance per liter of water

[2] Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023); considers compounds listed in the entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

[3] BfR recommendation XXI/1 as of 01.02.2023

Test results - specific migration of ammonium ion and elements in Annex II of EU No 10/2011

Test methods	Elements were analyzed using internal ICP-MS method; ammonium ion was analyzed using internal IC-method. For migration method and for preparation of the simulant, please see Page 4. Test performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable
Note	Results from the blank sample were subtracted from the original test results. For the content of elements in the blank water sample, please see **Annex I**.

Substance	Unit[1]	Result	Criteria[2]	Compliance[3]
Ammonium ion	mg/kg	< 0.002	≤ 60	compliant
Cadmium, Cd	mg/kg	< 0.002	≤ 0.002 (ND)	compliant
Arsenic, As	mg/kg	< 0.0025	≤ 0.01 (ND)	compliant
Chromium, Cr	mg/kg	< 0.0025	≤ 0.01 (ND)	compliant
Lead, Pb	mg/kg	< 0.0025	≤ 0.01 (ND)	compliant
Mercury, Hg	mg/kg	< 0.0025	≤ 0.01 (ND)	compliant
Nickel, Ni	mg/kg	0.011	≤ 0.02	compliant
Antimony, Sb	mg/kg	< 0.025	≤ 0.04	compliant
Cobalt, Co	mg/kg	< 0.0025	≤ 0.05	compliant
Europium, Eu	mg/kg	< 0.025	≤ 0.05	compliant
Gadolinium, Gd	mg/kg	< 0.025	≤ 0.05	compliant
Lanthanum, La	mg/kg	< 0.025	≤ 0.05	compliant
Terbium, Tb	mg/kg	< 0.025	≤ 0.05	compliant
Lithium, Li	mg/kg	< 0.025	≤ 0.6	compliant
Manganese, Mn	mg/kg	< 0.025	≤ 0.6	compliant
Aluminum, Al	mg/kg	< 0.025	≤ 1	compliant
Barium, Ba	mg/kg	0.006	≤ 1	compliant
Copper, Cu	mg/kg	< 0.025	≤ 5	compliant
Zinc, Zn	mg/kg	< 0.025	≤ 5	compliant
Iron, Fe	mg/kg	< 0.025	≤ 48	compliant
Calcium, Ca	mg/kg	7.69	≤ 60	compliant
Magnesium, Mg	mg/kg	1.72	≤ 60	compliant
Potassium, K	mg/kg	0.43	≤ 60	compliant
Sodium, Na	mg/kg	1.18	≤ 60	compliant
Sum of lanthanides, Eu, Gd, La, Tb	mg/kg	< 0.025	≤ 0.05	compliant

[1] The result is for mg of substance per liter of water.

[2] ND, not detected

[3] Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023) (confirms also compliance for BfR recommendation XXI/1 as of 01.02.2023)

Test results - specific migration of restricted substances

Test methods	Formaldehyde was analyzed with in-house HPLC-UV method. Vinyl chloride was analyzed with in-house GC Orbitrap method. For migration method and for preparation of the simulant, please see Page 4. Test performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable

Substance	FCM	CAS number	Unit[1]	Result	Criteria	Compliance[2]
Formaldehyde	98	50-00-0	mg/kg	< 1	≤ 15	compliant[2]
Formaldehyde	98	50-00-0	mg/L	< 1	≤ 3	compliant[3]
Vinyl chloride	127	75-01-4	mg/kg	< 0.01	≤ 0.01	compliant[2]

[1] The result is for mg of substance per liter of water.
[2] Commission Regulation (EU) 10/2011 on plastic materials and articles intended for contact with food, as amended (last update Regulation (EU) 2023/1627 of 10 August 2023).
[3] BfR recommendation XXI/1 as of 01.02.2023

Test results - specific migration of N-nitrosamines

Test methods	N-nitrosamines were analyzed using an internal LC Orbitrap method. For migration method and for preparation of the simulant, please see Page 4. Test performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable

Substance	CAS number	Unit[1]	Result	Criteria	Compliance[2]
N-nitroso-dimethylamine (NDMA)	17829-05-9	mg/kg	<0.01	-	-
N-nitroso-N-methyl-4-aminobutyric acid (NMBA)	61445-55-4	mg/kg	<0.01	-	-
N-nitrosodiethylamine (NDEA)	55-18-5	mg/kg	<0.01	-	-
N-ethyl-N-nitroso-2-propanamine (NEIPA)	16339-04-1	mg/kg	<0.01	-	-
N-nitroso-diisopropylamine (NDIPA)	601-77-4	mg/kg	<0.01	-	-
N-nitroso-di-n-propylamine (NDPA)	621-64-7	mg/kg	<0.01	-	-
N-nitroso-methylphenylamine (NMPA)	614-00-6	mg/kg	<0.01	-	-
N-nitroso-di-n-butylamine (NDBA)	924-16-3	mg/kg	<0.01	-	-
Sum of N-nitrosamines	-	mg/kg	<0.01	-	-
Sum of N-nitrosamines	-	µg/dm^2	< 1[3]	≤ 1	compliant

[1] The result is for mg of substance per liter of water.
[2] BfR recommendation XXI/1 as of 01.02.2023
[3] Result was converted to µg/dm^2 by first converting mg/kg (in water) to mg/dm^2 by using the conventional 6 dm^2/1 kg ratio. The result was further adjusted based on the total wetted area of EPDM rubber parts in comparison to the total wetted area of all parts of the instrument.

Test results - Specific migration of mineral oil hydrocarbons (MOSH/POSH, MOAH)

Test methods	The specific migration of mineral oil hydrocarbons (MOSH/POSH and MOAH) from the sample was analyzed according to an internal method using LC/GC-FID technique. The analytes were extracted from the simulant using liquid-liquid-extraction with hexane. Testing was performed by an ISO/IEC 17025 accredited external service provider.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable

MOSH/POSH group[1]	Unit[2]	Result
MOSH/POSH (C10 - C16)	mg/kg	<1
MOSH/POSH (C16 - C20)	mg/kg	<1
MOSH/POSH (C20 - C25)	mg/kg	<1
MOSH/POSH (C25 - C35)	mg/kg	<1
MOSH/POSH (C35 - C40)	mg/kg	<1
MOSH/POSH (C40 - C50)	mg/kg	<1
MOSH/POSH (C10 - C50) total[3]	**mg/kg**	**<1**

[1] MOSH/POSH are divided into groups based on the number of carbons in them.
[2] The result is for mg of substance per liter of water.
[3] Total content of MOSH/POSH compounds with 10 - 50 carbons

MOAH group[1]	Unit[2]	Result
MOAH (C10 - C16)	mg/kg	<1
MOAH (C16 - C25)	mg/kg	<1
MOAH (C25 - C35)	mg/kg	<1
MOAH (C35 - C50)	mg/kg	<1
MOAH (C10 - C50) total[3]	**mg/kg**	**<1**

[1] MOAH are divided into groups based on the number of carbons in them.
[2] The result is for mg of substance per liter of water.
[3] Total content of MOAH compounds with 10 - 50 carbons.

Test results - non-intentionally added substances

Test methods	GC Orbitrap and LC orbitrap screening for non-intentionally added substances (NIAS) according to internal method. For migration method and for preparation of the simulant, please see Page 4. Test performed by an ISO/IEC 17025 accredited external service provider. Evaluation of the compliance of the identified substances was performed by the external service provider and Measurlabs' expert.
Test conditions	For preparation of the simulant, see Page 4
Food simulant	For preparation of the simulant, see Page 4
Food contact surface area/ food simulant volume	Surface to volume ratio is not applicable
Results	All substances below the limit of interest (10 ppb); no risk assessment is required.

End of the test report

Annex I. Composition of the blank water sample

Substance / test parameter	Unit[1]	Result
Dry residue after evaporation	mg/kg	481
Antimony - Sb (CAS No. 7440-36-0)	µg/l	<25
Calcium - Ca (CAS No. 7440-70-2)	µg/l	87013.43
Europium - Eu (CAS No. 7440-53-1)	µg/l	<25
Gadolinium - Gd (CAS No. 7440-54-2)	µg/l	<25
Lanthanum - La (CAS No. 7439-91-0)	µg/l	<25
Magnesium - Mg (CAS No. 7439-95-4)	µg/l	33388.35
Terbium - Tb (CAS No. 7440-27-9)	µg/l	<25
Sodium - Na (CAS No. 7440-23-5)	µg/l	12996.71
Potassium - K (CAS No. 7440-09-7)	µg/l	4270.33
Lead - Pb (CAS No. 7439-92-1)	µg/l	2.897
Cadmium - Cd (CAS No. 7440-43-9)	µg/l	<2.5
Chromium - Cr (CAS No. 7440-47-3)	µg/l	<2.5
Arsenic - As (CAS No. 7440-38-2)	µg/l	<2.5
Nickel - Ni (CAS No. 7440-02-0)	µg/l	4.63
Manganese - Mn (CAS No. 7439-96-5)	µg/l	<25
Mercury - Hg (CAS No. 7439-97-6)	µg/l	<2.5
Zinc - Zn (CAS No. 7440-66-6)	µg/l	569.28
Aluminum - Al (CAS No.7429-90-5)	µg/l	<25
Barium - Ba (CAS No. 7440-39-3)	µg/l	85.36
Cobalt - Co (CAS No. 7440-48-4)	µg/l	<2.5
Copper - Cu (CAS No. 7440-50-8)	µg/l	91.05
Iron - Fe (CAS No. 7439-89-6)	µg/l	<25
Lithium - Li (CAS No. 7439-93-2)	µg/l	<25

[1] The result is for µg of substance per liter of water.