**Institute for
Interlaboratory Studies**

Results of Proficiency Test
Specific Migration on
Food Contact Materials
October 2023

Organized by: **Institute for Interlaboratory Studies**
Spijkenisse, the Netherlands

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1   INTRODUCTION

During the contact of materials with food, molecules can migrate from the food contact material to the food. Because of this, in many countries regulations are made to ensure food safety. The framework Regulation (EU) No. 10/2011 (lit. 13 and lit. 14) applies to all food contact materials and describes a large number of requirements, e.g. limits for Overall Migration and Specific Migration limits for certain constituents. The EU10/2011 regulation was amended regarding Metals in September 2020 with EU 2020/1245 (lit. 15) and was amended regarding Phthalates in July 2023 with EU 2023/1442 (lit 16).

Since 2012 the Institute of Interlaboratory Studies (iis) organizes a proficiency scheme for the determination of Specific Migration on Food Contact Materials every year. During the annual proficiency testing program of 2023 it was decided to continue the proficiency test for the determination of Specific Migration on Food Contact Materials.

In this interlaboratory study 32 laboratories in 17 countries registered for participation, see appendix 5 for the number of participants per country. In this report the results of the Specific Migration proficiency test are presented and discussed. This report is also electronically available through the iis website www.iisnl.com.

2   SET UP

The Institute for Interlaboratory Studies (iis) in Spijkenisse, the Netherlands, was the organizer of this proficiency test (PT). Sample analyzes for fit-for-use and homogeneity testing were subcontracted to a laboratory that has performed the tests in accordance with for ISO/IEC17043 relevant requirements of ISO/IEC17025.
It was decided to send two different samples. The first sample was a pink polypropylene cup labelled #23720 for the determination of migratable phthalates. The second sample was a black polycarbonate plate labelled #23721 for the determination of migratable metals.
The participants were requested to report rounded and unrounded test results. The unrounded test results were preferably used for statistical evaluation.

2.1   ACCREDITATION

The Institute for Interlaboratory Studies in Spijkenisse, the Netherlands, is accredited in agreement with ISO/IEC17043:2010 (R007), since January 2000, by the Dutch Accreditation Council (Raad voor Accreditatie). This PT falls under the accredited scope. This ensures strict adherence to protocols for sample preparation and statistical evaluation and 100% confidentiality of participant's data. Feedback from the participants on the reported data is encouraged and customer's satisfaction is measured on regular basis by sending out questionnaires.

2.2   PROTOCOL

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5). This protocol is electronically available through the iis website www.iisnl.com, from the FAQ page.

2.3   CONFIDENTIALITY STATEMENT

All data presented in this report must be regarded as confidential and for use by the participating companies only. Disclosure of the information in this report is only allowed by means of the entire report. Use of the contents of this report for third parties is only allowed by written permission of the Institute for Interlaboratory Studies. Disclosure of the identity of one or more of the participating companies will be done only after receipt of a written agreement of the companies involved.

2.4   SAMPLES

For the first sample a batch of pink polypropylene cups containing a detectable level of some Phthalates was prepared by a third party. The subsamples were labelled #23720.
The homogeneity of the subsamples was checked by determination of the Specific Migration of DEHP (Bis-2-ethylhexylphthalate) and DAP (Diallylphthalate) using an in house test method on 8 stratified randomly selected subsamples. Migration conditions: article filling, 50% M/V Ethanol, 1 hour at 70 °C.

	DEHP in mg/dm^2	DAP in mg/dm^2
sample #23720-1	0.2120	0.2338
sample #23720-2	0.2171	0.2374
sample #23720-3	0.2026	0.2403
sample #23720-4	0.1931	0.2171
sample #23720-5	0.2055	0.2193
sample #23720-6	0.2077	0.2127
sample #23720-7	0.2156	0.2360
sample #23720-8	0.1989	0.2244

Table 1: homogeneity test results of subsamples #23720

From the above test results the repeatabilities were calculated and compared with 0.3 times the corresponding estimated reproducibility calculated with the Horwitz equation in agreement with the procedure of ISO13528, Annex B2 in the next table.

	DEHP in mg/dm^2	DAP in mg/dm^2
r (observed)	0.0232	0.0295
reference method	Horwitz	Horwitz
0.3 x R (reference method)	0.0352	0.0382

Table 2: evaluation of the repeatabilities of subsamples #23720

The calculated repeatabilities are in agreement with 0.3 times the corresponding estimated reproducibility calculated with the Horwitz equation. Therefore, homogeneity of the subsamples was assumed.

For the second sample a batch of black polycarbonate plates containing a detectable level of some Metals was prepared by a third party. The subsamples were labelled #23721.
The homogeneity of the subsamples was checked by determination of the Specific Migration of Barium and Cobalt using an in house test method on 10 stratified randomly selected subsamples. Migration conditions: total immersion, 50% M/V Acetic Acid, 2 hours at 100 °C.

	Barium in mg/dm^2	Cobalt in mg/dm^2
sample #23721-1	0.2367	0.1125
sample #23721-2	0.2557	0.1245
sample #23721-3	0.2383	0.1066
sample #23721-4	0.2430	0.1131
sample #23721-5	0.2436	0.1151
sample #23721-6	0.2607	0.1153
sample #23721-7	0.2386	0.1076
sample #23721-8	0.2600	0.1233
sample #23721-9	0.2627	0.1253
sample #23721-10	0.2394	0.1147

Table 3: homogeneity test results of subsamples #23721

From the above test results the repeatabilities were calculated and compared with 0.3 times the corresponding estimated reproducibility calculated with the Horwitz equation in agreement with the procedure of ISO13528, Annex B2 in the next table.

	Barium in mg/dm^2	Cobalt in mg/dm^2
r (observed)	0.0296	0.0186
reference method	Horwitz	Horwitz
0.3 x R (reference method)	0.0411	0.0215

Table 4: evaluation of the repeatabilities of subsamples #23721

The calculated repeatabilities are in agreement with 0.3 times the corresponding estimated reproducibility calculated with the Horwitz equation. Therefore, homogeneity of the subsamples was assumed.

To each of the participating laboratories one cup labelled #23720 and one plate labelled #23721 were sent on September 6, 2023.

2.5   ANALYZES

The participants were requested to determine on sample #23720: 16 different Phthalates (BBP, DEHP, DBP, DIDP, DINP, DNOP, DCHP, DEP, DMP, DNHP, DIBP, DPHP, DNPP, DUP, DPRP and DAP) using the prescribed test conditions (article filling, single use, 1 hour at 70 °C and 50% M/V Ethanol as simulant).
For sample #23721 it was requested to determine: 9 different Metals (Aluminum as Al, Barium as Ba, Cobalt as Co, Copper as Cu, Iron as Fe, Lithium as Li, Manganese as Mn,

Nickel as Ni and Zinc as Zn) using the prescribed conditions (total immersion, single use, 2 hours at 100 °C and 3% M/V Acetic Acid as simulant).
It was also requested to report for both samples if the laboratory was accredited for the determined component and to report some analytical details.

It was explicitly requested to treat the samples as if they were routine samples and to report the test results using the indicated units on the report form and not to round the test results but report as much significant figures as possible. It was also requested not to report 'less than' test results, which are above the detection limit, because such test results cannot be used for meaningful statistical evaluations.

To get comparable test results a detailed report form and a letter of instructions are prepared. On the report form the reporting units are given as well as the reference test methods (when applicable) that will be used during the evaluation. The detailed report form and the letter of instructions are both made available on the data entry portal www.kpmd.co.uk/sgs-iis-cts/. The participating laboratories are also requested to confirm the sample receipt on this data entry portal. The letter of instructions can also be downloaded from the iis website www.iisnl.com.

3   RESULTS

During five weeks after sample dispatch, the test results of the individual laboratories were gathered via the data entry portal www.kpmd.co.uk/sgs-iis-cts/. The reported test results are tabulated per determination in appendices 1 and 2 of this report. The laboratories are presented by their code numbers.

Directly after the deadline, a reminder was sent to those laboratories that had not reported test results at that moment. Shortly after the deadline, the available test results were screened for suspect data. A test result was called suspect in case the Huber Elimination Rule (a robust outlier test) found it to be an outlier. The laboratories that produced these suspect data were asked to check the reported test results (no reanalyzes). Additional or corrected test results are used for data analysis and the original test results are placed under 'Remarks' in the result tables in appendices 1 and 2. Test results that came in after the deadline were not taken into account in this screening for suspect data and thus these participants were not requested for checks.

3.1   STATISTICS

The protocol followed in the organization of this proficiency test was the one as described for proficiency testing in the report 'iis Interlaboratory Studies: Protocol for the Organisation, Statistics and Evaluation' of June 2018 (iis-protocol, version 3.5).
For the statistical evaluation the *unrounded* (when available) figures were used instead of the rounded test results. Test results reported as '<…' or '>…' were not used in the statistical evaluation.

First, the normality of the distribution of the various data sets per determination was checked by means of the Lilliefors-test, a variant of the Kolmogorov-Smirnov test and by the calculation of skewness and kurtosis. Evaluation of the three normality indicators in

combination with the visual evaluation of the graphic Kernel density plot, lead to judgement of the normality being either 'unknown', 'OK', 'suspect' or 'not OK'. After removal of outliers, this check was repeated. If a data set does not have a normal distribution, the (results of the) statistical evaluation should be used with due care.

The assigned value is determined by consensus based on the test results of the group of participants after rejection of the statistical outliers and/or suspect data.

According to ISO13528 all (original received or corrected) results per determination were submitted to outlier tests. In the iis procedure for proficiency tests, outliers are detected prior to calculation of the mean, standard deviation and reproducibility. For small data sets, Dixon (up to 20 test results) or Grubbs (up to 40 test results) outlier tests can be used. For larger data sets (above 20 test results) Rosner's outlier test can be used. Outliers are marked by D(0.01) for the Dixon's test, by G(0.01) or DG(0.01) for the Grubbs' test and by R(0.01) for the Rosner's test. Stragglers are marked by D(0.05) for the Dixon's test, by G(0.05) or DG(0.05) for the Grubbs' test and by R(0.05) for the Rosner's test. Both outliers and stragglers were not included in the calculations of averages and standard deviations.

For each assigned value the uncertainty was determined in accordance with ISO13528. Subsequently the calculated uncertainty was evaluated against the respective requirement based on the target reproducibility in accordance with ISO13528. In this PT the criterion of ISO13528, paragraph 9.2.1, was met for all evaluated tests. Therefore, the uncertainty of all assigned values may be negligible and need not be included in the PT report.

Finally, the reproducibilities were calculated from the standard deviations by multiplying them with a factor of 2.8.

3.2 GRAPHICS

In order to visualize the data against the reproducibilities from literature, Gauss plots were made, using the sorted data for one determination (see appendix 1). On the Y-axis the reported test results are plotted. The corresponding laboratory numbers are on the X-axis. The straight horizontal line presents the consensus value (a trimmed mean). The four striped lines, parallel to the consensus value line, are the +3s, +2s, -2s and -3s target reproducibility limits of the selected reference test method. Outliers and other data, which were excluded from the calculations, are represented as a cross. Accepted data are represented as a triangle.

Furthermore, Kernel Density Graphs were made. This is a method for producing a smooth density approximation to a set of data that avoids some problems associated with histograms. Also, a normal Gauss curve (dotted line) was projected over the Kernel Density Graph (smooth line) for reference. The Gauss curve is calculated from the consensus value and the corresponding standard deviation.

3.3   Z-SCORES

To evaluate the performance of the participating laboratories the z-scores were calculated. As it was decided to evaluate the performance of the participants in this proficiency test (PT) against the literature requirements (derived from e.g. ISO or ASTM test methods), the z-scores were calculated using a target standard deviation. This results in an evaluation independent of the variation in this interlaboratory study.

The target standard deviation was calculated from the literature reproducibility by division with 2.8. In case no literature reproducibility was available, other target values were used, like Horwitz or an estimated reproducibility based on former iis proficiency tests.

When a laboratory did use a test method with a reproducibility that is significantly different from the reproducibility of the reference test method used in this report, it is strongly advised to recalculate the z-score, while using the reproducibility of the actual test method used, this in order to evaluate whether the reported test result is fit-for-use.

The z-scores were calculated according to:

$$z_{(target)} = (\text{test result - average of PT}) / \text{target standard deviation}$$

The $z_{(target)}$ scores are listed in the test result tables in appendix 1.

Absolute values for z<2 are very common and absolute values for z>3 are very rare. Therefore, the usual interpretation of z-scores is as follows:

$$|z| < 1 \quad \text{good}$$
$$1 < |z| < 2 \quad \text{satisfactory}$$
$$2 < |z| < 3 \quad \text{questionable}$$
$$3 < |z| \quad \text{unsatisfactory}$$

4   EVALUATION

In this proficiency test no problems were encountered with the dispatch of the samples. Three participants reported test results after the final reporting date and two other participants did not report any test results. Not all participants were able to report all tests requested.
In total 30 participants reported 106 numerical test results for Specific Migration per contact surface. Observed were 10 outlying test results, which is 9.4%. In proficiency studies outlier percentages of 3% - 7.5% are quite normal.

Not all data sets proved to have a normal Gaussian distribution. These are referred to as "not OK" or "suspect". The statistical evaluation of these data sets should be used with due care, see also paragraph 3.1.

4.1   EVALUATION PER SAMPLE AND PER COMPONENT

In this section the reported test results are discussed per sample and per component. The test methods which were used by the various laboratories were taken into account for explaining the observed differences when possible and applicable. These test methods are also in the tables together with the original data in appendix 1. The abbreviations, used in these tables, are explained in appendix 6.

In the past iis has observed that for the Overall and Specific Migration methods, limits and calculations are mixed up and used inappropriately by participants. Therefore, iis issued a White Paper on this subject in February 2018 (see lit. 17) to help participants understand the differences between the two methods, the units used for reporting and the regulated limits.

For the determination of Specific Migration, several test methods exist. The most relevant test method is method EN13130 part 1. Method EN13130 part 1 describes how the Specific Migration test should be performed. Regretfully, no reference test method is available with precision requirements for the migration of Phthalates and Metals from food contact materials in mg/dm^2. Therefore, it was decided to estimate the target reproducibilities calculated from the Horwitz equation. The reported test results of the Specific Migration per contact surface in mg/dm^2 were used for the statistical evaluation.

sample #23720

DEHP: The group of participants may have had difficulty to meet the target requirements. No statistical outliers were observed. The calculated reproducibility is not at all in agreement with the estimated reproducibility calculated with the Horwitz equation.

DAP: The group of participants may have had difficulty to meet the target requirements. No statistical outliers were observed. The calculated reproducibility is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

The majority of participants agreed on a concentration near or below the limit of detection for the other requested phthalates mentioned in paragraph 2.5. Therefore, no z-scores are calculated for these phthalates. The reported test results in mg/dm^2 are given in appendix 2.

sample #23721

Aluminum: The group of participants may have had difficulty to meet the target requirements. Three statistical outliers were observed and one other test result was excluded. The calculated reproducibility after rejection of the suspect data is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Barium: The group of participants may have had difficulty to meet the target requirements. Three statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is not in agreement with the estimated reproducibility calculated with the Horwitz equation.

Cobalt:　　　　The group of participants met the target requirements. Four statistical outliers were observed. The calculated reproducibility after rejection of the statistical outliers is in agreement with the estimated reproducibility calculated with the Horwitz equation.

The majority of participants agreed on a concentration near or below the limit of detection for the other requested metals mentioned in paragraph 2.5. Therefore, no z-scores are calculated for these metals. The reported test results in mg/dm^2 are given in appendix 2.

4.2　Performance evaluation for the group of laboratories

A comparison has been made between the reproducibility as declared by the reference test method and the reproducibility as found for the group of participating laboratories. The number of significant test results, the average, the calculated reproducibility (2.8 * standard deviation) and the target reproducibility derived from reference methods are presented in the next tables.

Component	unit	n	average	2.8 * sd	R(target)
DEHP	mg/dm^2	21	0.185	0.373	0.107
DAP	mg/dm^2	13	0.254	0.334	0.140

Table 5: reproducibilities of components on sample #23720

Component	unit	n	average	2.8 * sd	R(target)
Aluminum	mg/dm^2	14	0.018	0.018	0.015
Barium	mg/dm^2	24	0.224	0.167	0.126
Cobalt	mg/dm^2	23	0.095	0.065	0.061

Table 6: reproducibilities of components on sample #23721

Without further statistical calculations it can be concluded that for many components there is not a good compliance of the group of participants with the reference method. The problematic components have been discussed in paragraph 4.1.

4.3　Comparison of proficiency test of October 2023 with previous PTS

	October 2023	October 2022	October 2021	October 2020	September 2019
Number of reporting laboratories	30	35	19	24	18
Number of test results	106	262	117	104	26
Number of statistical outliers	10	23	6	11	3
Percentage of statistical outliers	9.4%	8.8%	5.1%	10.6%	11.5%

Table 7: comparison with previous proficiency tests

In proficiency tests outlier percentages of 3% - 7.5% are quite normal.

The performance of the determinations of the proficiency test was compared to uncertainties observed in PTs over the years, expressed as relative standard deviation (RSD) of the PTs, see next table.

Year	Components	Type of migration	Observed RSD%	Target RSD%	Concentration range mg/dm^2
2012	Formaldehyde	article filling	41 – 47	20 – 140	3 – 0.2
2013	Formaldehyde	article filling	41 – 61	14 – 20	3 – 0.2
2014	Bisphenol-A	total immersion	44 – 52	14 – 20	3 – 0.2
2015	DEHP	total immersion	34 – 40	14 – 20	3 – 0.2
2016	Metals	total immersion	29 – 30	14 – 20	3 – 0.2
2017	Bisphenol-A	article filling	33 – 50	20 – 33	0.2 – 0.009
2018	Metals	article filling	21 – 35	17 – 38	0.6 – 0.003
2019	DEHP/DAP	article filling	24 – 34	19 – 20	0.34 – 0.20
2020	Formaldehyde	article filling	28 – 51	17 – 19	0.62 – 0.32
	Metals	article filling	17 – 20	19 – 20	0.32 – 0.22
2021	MDA	article filling	70 – 84	41 – 82	0.008 – 0.004
	Metals	total immersion	18 – 44	17 – 26	0.6 – 0.04
2022	Bisphenol A	total immersion	16 – 22	18 – 20	0.43 – 0.22
	Metals	article filling	19 – 29	21 – 26	0.19 – 0.04
2023	DEHP/DAP	article filling	47 – 72	20 – 21	0.25 – 0.19
	Metals	total immersion	24 – 37	20 – 29	0.22 – 0.018

Table 8: development of the uncertainties over the years

The uncertainties observed in this PT are for Metals in line with the uncertainties observed in previous PTs. However, the uncertainties for DEHP/DAP are not in line.

4.4 EVALUATION OF THE ANALYTICAL DETAILS

Before the start of this PT it was clear that a wide range of test results would be reported when the choice of the test conditions would have been selected by the participating laboratories. Therefore, a set of prescribed test conditions (known to give a positive test result) was given together with the instructions to all participants:

Sample code	#23720	#23721
Sample type	pink polypropylene cup containing some Phthalates	black polypropylene plate containing some heavy Metals
Simulant	50% M/V Ethanol	3% M/V Acetic Acid
Time of exposure	1 hour	2 hours
Temperature of exposure	70 °C	100 °C
Method of migration	Article filling, single use	Total immersion, single use
Volume of simulant	as per method used	as per method used

Table 9: prescribed test conditions in this PT

For both samples the participants were requested to report the Specific Migration in mg/dm^2 per contact surface as well as the intermediate test results (the final concentration in mg/L in simulant). Additional details regarding surface area, simulant volume and details about the evaporation step were also requested. See appendices 3 and 4.

For sample #23720 nine of the reporting participants mentioned that they are accredited for this test. Six of the reporting participants mentioned to have used test method EN13130-1 or EN13130, ten participants mentioned to have used an in house method.
Two participants reported to use water to clean the test item which is not in line with test method EN13130-1 paragraph 19.5.
Most of the participants used a surface area between 1.3 dm^2 and 1.9 dm^2. Two participants used a surface area below 1 dm^2 and one participant above 2 dm^2. Most of the participants used a volume of simulant between 200 mL and 250 mL. Three participants used a volume below 200 mL and one participant above 250 mL.

For sample #23721 eighteen of the reporting participants mentioned that they are accredited for this test. Seventeen of the reporting participants mentioned to have used test method EN13130-1 or EN13130, seven participants mentioned to have used an in house method.
Five participants reported to use water to clean the test item which is not in line with test method EN13130-1 paragraph 15.5.
Most of the participants used a surface area between 1.9 dm^2 and 2.2 dm^2. Four participants used a surface area between 0.3 dm^2 and 1 dm^2. Most of the participants used a volume of simulant between 200 mL and 250 mL. Three participants used a volume below 200 mL and one participant above 250 mL. In general, most of the participants used a contact surface/volume of simulant ratio of 0.6 dm^2/100 mL. It is remarkable that the participants mention a different surface area for the same volume used.

For sample #23720 and for sample #23721 most of the participants preheated the simulant solution and most of the participants used an oven as equipment.
Most of the participants reported to use a seal during the test. Several different types of seals were reported by the participants, e.g. a plastic film/foil, an aluminum film, a glass plate/watch or an airtight container.

None of the above details have shown an apparent influence on the test results in this PT.

5   DISCUSSION

The limits for specific migration for Phthalates (see table 10) and Metals (see table 11) are mentioned in mg/kg food or food simulant. It is mentioned in EN13130-1 that the limits expressed in mg/kg food shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm^2, see next tables.

Component	Specific Migration Limit in mg/kg food	Specific Migration Limit in mg/dm^2
DEHP	0.6	0.1
DAP	shall not migrate in detectable quantities	shall not migrate in detectable quantities

Table 10: Specific Migration maximum limits according to EU 2023/1442

Component	Specific Migration Limit in mg/kg food or food simulant	Specific Migration Limit in mg/dm^2
Aluminum	1	0.167
Barium	1	0.167
Cobalt	0.05	0.008
Copper	5	0.833
Iron	48	8
Lithium	0.6	0.1
Manganese	0.6	0.1
Nickel	0.02	0.003
Zinc	5	0.833

Table 11: Specific Migration maximum limits according to EU 2020/1245 (ANNEX II)

Fifteen participants would have rejected sample #23720 for DEHP, while six participants would have accepted the sample for DEHP.

All reporting participants (except one) would have accepted sample #23721 for Aluminum. Almost all reporting participants would have rejected sample #23721 for Barium, while two participants would have accepted the sample for Barium.
All reporting participants would have rejected sample #23721 for Cobalt.

6   CONCLUSION

It is to be expected that the variation of the migration results in real practice will be larger than observed in thit PT as the test conditions like time, temperature, etc. will not be prescribed but will be selected by the individual laboratories.

Each participating laboratory will have to evaluate its performance in this study and decide about any corrective actions if necessary. Therefore, participation on a regular basis in this scheme could be helpful to improve the performance and thus increase of the quality of the analytical results.

APPENDIX 1

Determination of Specific Migration of DEHP - Bis-2-ethylhexylphthalate on sample #23720; results in mg/dm^2 per contact surface

lab	method	value	mark	z(targ)	remarks
339		0.289	C	2.72	first reported 1.3125
362	In house	0.12	C,E	-1.70	first reported 3.57; calculation difference, iis calc. 3.57
551		-----		-----	
2108	In house	0.2713		2.26	
2115	In house	0.00149	E	-4.81	calculation difference, iis calculated 0.00996
2132	EN13130	0.20		0.39	
2300	EN13030-1	0.0265		-4.15	
2353		0.258		1.91	
2365	GB31604.30	0.2300		1.18	
2366		-----		-----	
2384	In house	0.2161		0.81	
2385	EN13030-1	0.3562		4.48	
2475	In house	0.4017		5.68	
2482		-----		-----	
2500		-----		-----	
2510		-----		-----	
2515	EN13030-1	0.11669		-1.79	
2553		-----		-----	
2797	In house	0.054		-3.43	
2826	In house	0.2689		2.20	
2897		-----		-----	
2901		-----		-----	
2925		-----		-----	
2976	EN13030-1	0.068		-3.07	
3002	EPA3510/8270E	0.023		-4.25	
3017	CPSC-CH-C1001-09.4/-09.3	0.0624		-3.21	
3024	EPA8061	0.1183		-1.75	
3028	In house	>0.02674		-----	
3122	In house	0.2		0.39	
3134	In house	0.492		8.04	
3172	EN13030-1	0.1126		-1.90	
3182		-----		-----	
	normality	OK			
	n	21			
	outliers	0			
	mean (n)	0.1851			
	st.dev. (n)	0.13306	RSD = 72%		
	R(calc.)	0.3726			
	st.dev.(Horwitz)	0.03817			
	R(Horwitz)	0.1069			
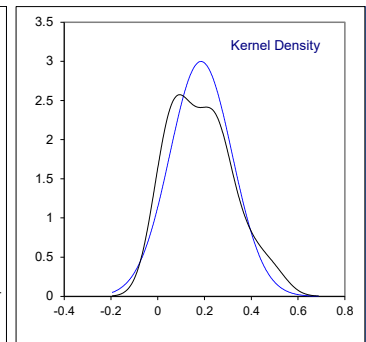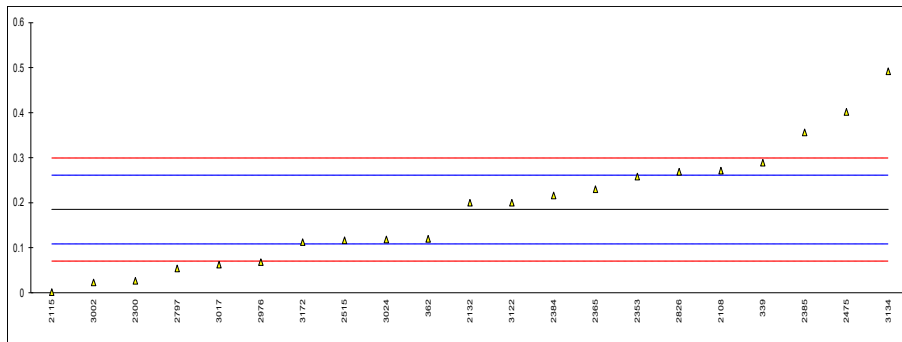
Determination of Specific Migration of DAP – Diallylphthalate on sample #23720; results in mg/dm^2 per contact surface

lab	method	value	mark	z(targ)	remarks
339		0.282	C	0.56	first reported 1.284
362		-----		-----	
551		-----		-----	
2108	In house	0.4226		3.38	
2115		-----		-----	
2132		-----		-----	
2300	EN13030-1	0.0628		-3.83	
2353		0.235		-0.38	
2365	GB31604.30	0.2036		-1.01	
2366		-----		-----	
2384	In house	0.1326		-2.43	
2385	EN13030-1	0.2766		0.45	
2475	In house	0.3756		2.44	
2482		-----		-----	
2500		-----		-----	
2510		-----		-----	
2515		-----		-----	
2553		-----		-----	
2797		-----		-----	
2826	In house	0.3138		1.20	
2897		-----		-----	
2901		-----		-----	
2925		-----		-----	
2976		-----		-----	
3002		-----		-----	
3017		-----		-----	
3024	EPA8061	0.1996		-1.09	
3028	In house	>0.02674		-----	
3122	In house	0.2		-1.08	
3134	In house	0.470		4.33	
3172	EN13030-1	0.1270		-2.54	
3182		-----		-----	
	normality	OK			
	n	13			
	outliers	0			
	mean (n)	0.2539			
	st.dev. (n)	0.11935	RSD = 47%		
	R(calc.)	0.3342			
	st.dev.(Horwitz)	0.04994			
	R(Horwitz)	0.1398			
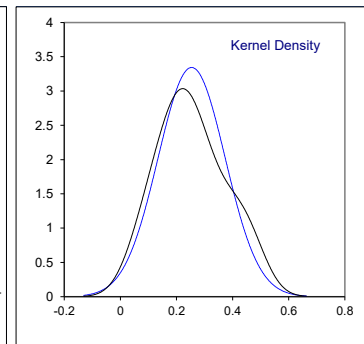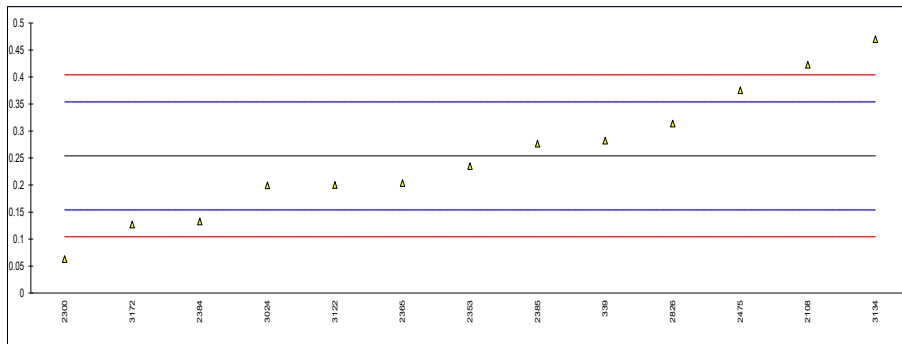
Determination of Specific Migration of Aluminum as Al on sample #23721; results in mg/dm^2 per contact surface

lab	method	value	mark	z(targ)	remarks
339		0.166	E,G(0.05)	28.17	calculation difference, iis calc. 0.028; possibly reported in mg/kg?
362		-----		-----	
551		-----		-----	
2108		0.00583		-2.30	
2115		-----		-----	
2132	EN13130-1	0.01589		-0.39	
2300	EN13130-1	0.16	G(0.01)	27.02	
2353	EN13130-1	ND		-----	
2365	EN13130-1	0.01714	C	-0.15	first reported 0.102854
2366	EN13130-1	0.0177		-0.05	
2384	EN13130-1	<0.04		-----	
2385	EN13130-1	0.02475		1.30	
2475	EN13130-1	0.0110		-1.32	
2482		-----		-----	
2500		-----		-----	
2510	In house	0.0330		2.87	
2515	EN13130-1	<0.01665		-----	
2553		-----		-----	
2797	In house	0.0189		0.18	
2826	EN13130-1	Not detected		-----	
2897	EN13130-1	0.0177		-0.05	
2901	EN13130-1	0.0197		0.34	
2925	In house	0.0149		-0.58	
2976	In house	1.039	C,G(0.01)	194.24	first reported 25.98
3002	In house	0.019		0.20	
3017	EN1186-1/-7	-----		-----	
3024	EN13130-1	0.011617		-1.20	
3028		-----		-----	
3122	In house	0.0505	ex	6.19	test results excluded: two statistical outliers in related parameters
3134		-----		-----	
3172	EN13130-1	< 0.03		-----	
3182	EN13130-1	0.024		1.15	

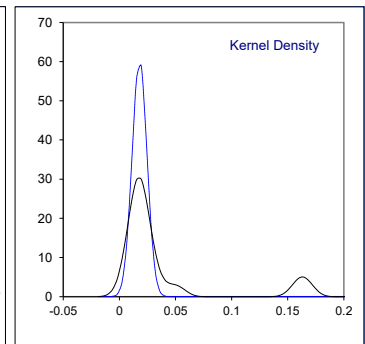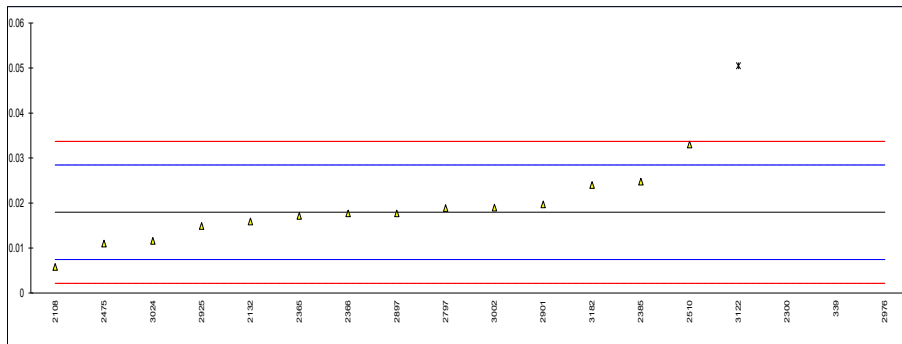|			
normality	suspect		
n	14		
outliers	3 + 1ex		
mean (n)	0.0179		
st.dev. (n)	0.00659	RSD = 37%	
R(calc.)	0.0184		
st.dev.(Horwitz)	0.00526		
R(Horwitz)	0.0147		

Determination of Specific Migration of Barium as Ba on sample #23721; results in mg/dm² per contact surface

lab	method	value	mark	z(targ)	remarks
339		1.682	E,R(0.01)	32.48	calculation difference, iis calc. 0.280; possibly reported in mg/kg?
362	In house	0.208		-0.36	
551		-----		-----	
2108		0.20866		-0.34	
2115	EN13130	0.847	R(0.01)	13.88	
2132	EN13130-1	0.1653		-1.31	
2300	EN13130-1	0.06		-3.65	
2353	EN13130-1	0.271		1.05	
2365	EN13130-1	0.24200	C	0.40	first reported 1.45201
2366	EN13130-1	0.245		0.47	
2384	EN13130-1	0.327		2.29	
2385	EN13130-1	0.1667		-1.28	
2475	EN13130-1	0.1878		-0.81	
2482	EN13130-1	0.1889		-0.78	
2500		-----		-----	
2510	In house	0.2612		0.83	
2515	EN13130-1	0.28994		1.47	
2553		-----		-----	
2797	In house	0.2638	E	0.89	calculation difference, iis calulated 0.2837
2826	EN13130-1	0.242		0.40	
2897	EN13130-1	0.2735		1.10	
2901	EN13130-1	0.3007		1.71	
2925	In house	0.2295		0.12	
2976	In house	0.2	C	-0.53	first reported 5.00
3002	In house	0.263		0.87	
3017	EN1186-1/-7	0.1165		-2.39	
3024	EN13130-1	0.188333		-0.79	
3028		-----		-----	
3122	In house	0.5936	R(0.01)	8.23	
3134		-----		-----	
3172	EN13130-1	0.223		-0.02	
3182	EN13130-1	0.254		0.67	

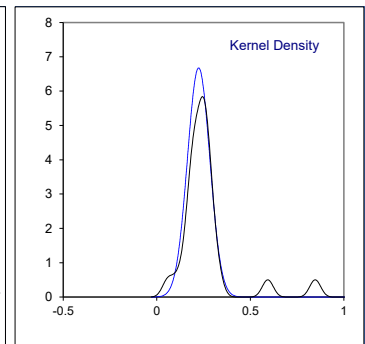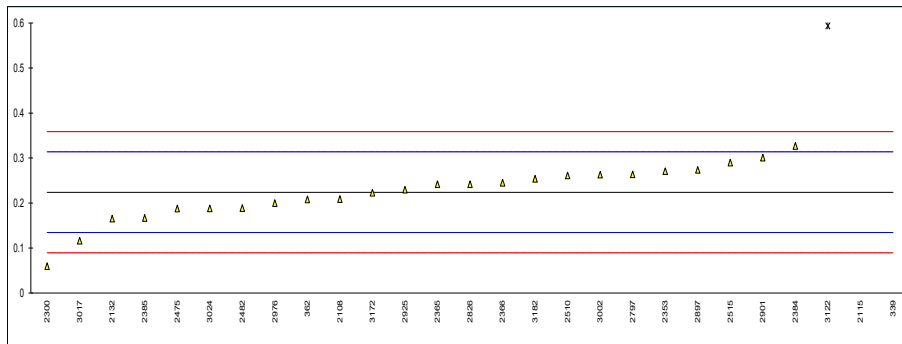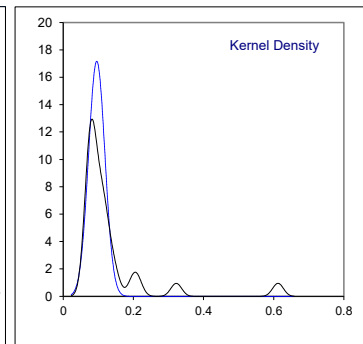|				
normality	suspect			
n	24			
outliers	3			
mean (n)	0.2240			
st.dev. (n)	0.05974	RSD = 27%		
R(calc.)	0.1673			
st.dev.(Horwitz)	0.04489			
R(Horwitz)	0.1257			

Determination of Specific Migration of Cobalt as Co on sample #23721; results in mg/dm^2 per contact surface

lab	method	value	mark	z(targ)	remarks
339		0.612	E,R(0.01)	23.76	calculation difference, iis calc. 0.102; possibly reported in mg/kg?
362	In house	0.07		-1.17	
551		-----		-----	
2108		0.06938		-1.20	
2115	EN13130	0.322	R(0.01)	10.42	
2132	EN13130-1	0.08027		-0.70	
2300	EN13130-1	0.08		-0.71	
2353	EN13130-1	0.105		0.44	
2365	EN13130-1	0.07929	C	-0.74	first reported 0.47573
2366	EN13130-1	0.0855		-0.46	
2384	EN13130-1	0.149		2.46	
2385	EN13130-1	0.0749		-0.94	
2475	EN13130-1	0.0809		-0.67	
2482	EN13130-1	0.06961		-1.19	
2500		-----		-----	
2510	In house	0.1223		1.24	
2515	EN13130-1	0.13922		2.01	
2553		-----		-----	
2797	In house	0.1239		1.31	
2826	EN13130-1	0.114		0.85	
2897	EN13130-1	0.1090		0.62	
2901	EN13130-1	0.1056		0.47	
2925	In house	0.08795		-0.34	
2976	In house	0.078	C	-0.80	first reported 1.95
3002	In house	0.095		-0.02	
3017	EN1186-1/-7	0.2112	R(0.01)	5.32	
3024	EN13130-1	0.073407		-1.01	
3028		-----		-----	
3122	In house	0.1990	R(0.01)	4.76	
3134		-----		-----	
3172	EN13130-1	0.1166		0.97	
3182	EN13130-1	0.086		-0.43	

normality	OK	
n	23	
outliers	4	
mean (n)	0.0954	
st.dev. (n)	0.02324	RSD = 24%
R(calc.)	0.0651	
st.dev.(Horwitz)	0.02175	
R(Horwitz)	0.0609	
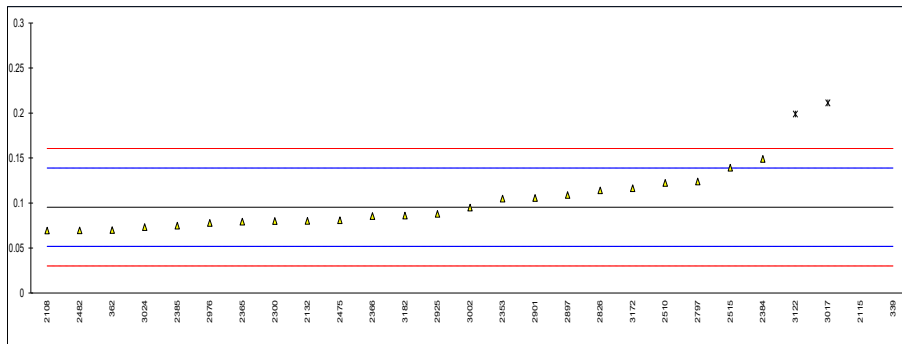
APPENDIX 2 Other reported test results

Sample #23720

Determination of Specific Migration of other phthalates; results in mg/dm^2

lab	BBP	DBP	DIDP	DINP	DNOP	DCHP	DEP
339	<0.1	<0.1	<0.5	<0.5	na	na	na
362	-----	0.286	-----	-----	-----	-----	-----
551	-----	-----	-----	-----	-----	-----	-----
2108	not detected	not detected	not detected	not detected	not detected	not detected	not detected
2115	-----	-----	-----	-----	-----	-----	-----
2132	<1.0	<0.1	<1.0	<1.0	-----	-----	-----
2300	not detected	0.0265	not detected	not detected	not detected	not detected	0.435
2353	ND	ND	ND	ND	NA	NA	NA
2365	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123
2366	-----	-----	-----	-----	-----	-----	-----
2384	Not detected	Not detected	Not detected	Not detected	Not analyzed	Not detected	Not detected
2385	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007
2475	-----	-----	-----	-----	-----	-----	-----
2482	-----	-----	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----	-----	-----
2510	-----	-----	-----	-----	-----	-----	-----
2515	<0.0013	<0.0013	<0.0013	<0.0013	-----	-----	-----
2553	-----	-----	-----	-----	-----	-----	-----
2797	-----	-----	-----	-----	-----	-----	-----
2826	Not detected	Not detected	Not detected	Not detected	-----	-----	-----
2897	-----	-----	-----	-----	-----	-----	-----
2901	-----	-----	-----	-----	-----	-----	-----
2925	-----	-----	-----	-----	-----	-----	-----
2976	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
3002	not detected	not detected	not detected	not detected	not detected	not detected	not detected
3017	not detected	not detected	not detected	0.0432	not detected	not detected	not detected
3024	Not Detected	0.0014	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
3028	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107
3122	nd	nd	nd	nd	nd	nd	nd
3134	not detected	not detected	not detected	below LOQ	not detected	not analysed	not detected
3172	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014
3182	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed

Determination of Specific Migration of other phthalates; results in mg/dm^2 -- continued --

lab	DMP	DNHP	DIBP	DPHP	DNPP	DUP	DPRP
339	na	na	na	na	na	na	na
362	-----	-----	-----	-----	-----	-----	-----
551	-----	-----	-----	-----	-----	-----	-----
2108	not detected	not detected	not detected	not detected	not detected	not detected	not detected
2115	-----	-----	-----	-----	-----	-----	-----
2132	-----	-----	-----	-----	-----	-----	-----
2300	not detected	not detected	not detected	not detected	not detected	not detected	not detected
2353	NA	NA	ND	NA	NA	NA	NA
2365	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123	<0.0123
2366	-----	-----	-----	-----	-----	-----	-----
2384	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
2385	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007	< 0.007
2475	-----	-----	-----	-----	-----	-----	-----
2482	-----	-----	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----	-----	-----
2510	-----	-----	-----	-----	-----	-----	-----
2515	-----	-----	<0.0013	-----	-----	-----	-----
2553	-----	-----	-----	-----	-----	-----	-----
2797	-----	-----	-----	-----	-----	-----	-----
2826	-----	-----	Not detected	-----	-----	-----	-----
2897	-----	-----	-----	-----	-----	-----	-----
2901	-----	-----	-----	-----	-----	-----	-----
2925	-----	-----	-----	-----	-----	-----	-----
2976	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
3002	not detected	not detected	not detected	not detected	not detected	not detected	not detected
3017	not detected	not detected	not detected	not detected	not detected	not applicable	not applicable
3024	Not Detected	Not Detected	Not Detected	Not Analyzed	Not Detected	Not Analyzed	Not Analyzed
3028	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107	<0.00107
3122	0.13	nd	nd	nd	nd	nd	nd
3134	not detected	not analysed	not detected	not analysed	not analysed	not analysed	not analysed
3172	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014	< 0.014
3182	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed

Sample #23721

Determination of Specific Migration of other elements; results in mg/dm^2

lab	Copper (Cu)	Iron (Fe)	Lithium (Li)	Manganese (Mn)	Nickel (Ni)	Zinc (Zn)
339	0.001	0.005	0	0	0.001	0.011
362	-----	-----	-----	-----	-----	-----
551	-----	-----	-----	-----	-----	-----
2108	not detected	not detected	not detected	0.00137	not detected	not detected
2115	-----	-----	-----	-----	-----	0.012
2132	0.0002140	0.001452	<0.1	0.00004627	0.0004089	0.001107
2300	not detected	0.03	not detected	not detected	0.005	0.013
2353	ND	ND	ND	ND	ND	ND
2365	<0.25	<5	<0.1	<0.1	<0.01	<0.5
2366	<0.0417	<0.833	<0.0167	<0.0167	<0.00167	<0.0833
2384	<0.04	<0.04	<0.08	<0.04	<0.002	<0.08
2385	<0.001	<0.001	<0.001	<0.001	<0.001	0.0038
2475	-----	0.0025	-----	-----	-----	0.0030
2482	-----	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----	-----
2510	Below LOQ	Below LOQ	Below LOQ	Below LOQ	Below LOQ	0.0399
2515	<0.0033	<0.0033	<0.0008	<0.0008	<0.0008	<0.0033
2553	-----	-----	-----	-----	-----	-----
2797	not determined	not determined	not determined	not determined	not determined	not determined
2826	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
2897	not detected	not detected	not detected	not detected	0.0003	not detected
2901	-----	-----	-----	-----	-----	-----
2925	ND	ND	ND	ND	ND	ND
2976	Not Detected	Not Detected	-----	Not Detected	Not Detected	Not Detected
3002	not detected	not detected	not detected	not detected	not detected	0.030
3017	not detected	0.0045	not detected	not detected	not detected	not detected
3024	0.002018	0.001764	Not Detected	Not Detected	Not Detected	0.004939
3028	-----	-----	-----	-----	-----	-----
3122	nd	nd	nd	nd	nd	nd
3134	-----	-----	-----	-----	-----	-----
3172	< 0.166	< 1.666	< 0.0166	< 0.0166	< 0.00166	< 0.0833
3182	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected

APPENDIX 3 Details on reported intermediate test results

sample #23720 Surface area, volume of simulant and final concentrations in mg/L

lab	surface area (dm²)	volume simulant (mL)	final concentration in simulant (mg/L)				
			BBP	DEHP	DBP	DIDP	DINP
339	1.60	220	<0.1	2.10	<0.1	<0.5	<0.5
362	1.61	230	-----	25	2	-----	-----
551	-----	-----	-----	-----	-----	-----	-----
2108	1.75	200	not detected	2.374	not detected	not detected	not detected
2115	1.58	200	-----	0.07867	-----	-----	-----
2132	1.60	250	<1.0	1.29	<0.1	<1.0	<1.0
2300	1.72	240	not detected	0.19	0.21	not detected	not detected
2353	1.5438	220	ND	1.81	ND	ND	ND
2365	1.62	200	<0.1	1.86	<0.1	<0.1	<0.1
2366	-----	-----	-----	-----	-----	-----	-----
2384	1.8	200 C	Not detected	1.9453	Not detected	Not detected	Not detected
2385	1.7	230	< 0,05	2.6344	< 0.05	< 0.05	< 0.05
2475	1.74	250	-----	2.7955	-----	-----	-----
2482	-----	-----	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----	-----	-----
2510	-----	-----	-----	-----	-----	-----	-----
2515	1.513	200	<0.01	0.8813	<0.01	<0.01	<0.01
2553	-----	-----	-----	-----	-----	-----	-----
2797	1.393	180	-----	0.41828	-----	-----	-----
2826	1.618	240	Not detected	1.815	Not detected	Not detected	Not detected
2897	-----	-----	-----	-----	-----	-----	-----
2901	-----	-----	-----	-----	-----	-----	-----
2925	-----	-----	-----	-----	-----	-----	-----
2976	2.32	240	Not Detected	0.66	Not Detected	Not Detected	Not Detected
3002	1.5	250	not detected	0.141	not detected	not detected	not detected
3017	0.250	100	not detected	0.1561	not detected	not detected	0.1083
3024	0.9570	100.00	Not Detected	1.1325	0.0137	Not Detected	Not Detected
3028	1.87	200	<0.010	>0.250	<0.010	<0.010	<0.010
3122	1.7	266	nd	1.25	nd	nd	nd
3134	1.667	250	not detected	3.282	not detected	not detected	below LOQ
3172	1.4334	200	< 0.1	0.8069	< 0.1	< 0.1	< 0.1
3182	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed

Lab 2384 reported 2000 mL

sample #23720 Surface area, volume of simulant and final concentrations in mg/L -- continued --

lab	DNOP	DCHP	DEP	DMP	DNHP	DIBP
	final concentration in simulant (mg/L)					
339	na	na	na	na	na	na
362	-----	-----	-----	-----	-----	-----
551	-----	-----	-----	-----	-----	-----
2108	not detected	not detected	not detected	not detected	not detected	not detected
2115	-----	-----	-----	-----	-----	-----
2132	-----	-----	-----	-----	-----	-----
2300	not detected	not detected	3.12	not detected	not detected	not detected
2353	NA	NA	NA	NA	NA	ND
2365	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
2366	-----	-----	-----	-----	-----	-----
2384	Not analyzed	Not detected	Not detected	Not detected	Not detected	Not detected
2385	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
2475	-----	-----	-----	-----	-----	-----
2482	-----	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----	-----
2510	-----	-----	-----	-----	-----	-----
2515	-----	-----	-----	-----	-----	<0.01
2553	-----	-----	-----	-----	-----	-----
2797	-----	-----	-----	-----	-----	-----
2826	-----	-----	-----	-----	-----	Not detected
2897	-----	-----	-----	-----	-----	-----
2901	-----	-----	-----	-----	-----	-----
2925	-----	-----	-----	-----	-----	-----
2976	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
3002	not detected	not detected	not detected	not detected	not detected	not detected
3017	not detected	not detected	not detected	not detected	not detected	not detected
3024	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
3028	<0.010	<0.010	<0.010	<0.010	<0.010	<0.010
3122	nd	nd	nd	0.86	nd	nd
3134	not detected	not analysed	not detected	not detected	not analysed	not detected
3172	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
3182	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed

sample #23720 Surface area, volume of simulant and final concentrations in mg/L -- continued --

lab	DHPH	DNPP	DUP	DPRP	DAP
	final concentration in simulant (mg/L)				
339	na	na	na	na	2.054
362	-----	-----	-----	-----	-----
551	-----	-----	-----	-----	-----
2108	not detected	not detected	not detected	not detected	3.698
2115	-----	-----	-----	-----	-----
2132	-----	-----	-----	-----	-----
2300	not detected	not detected	not detected	not detected	0.45
2353	NA	NA	NA	NA	1.65
2365	<0.1	<0.1	<0.1	<0.1	1.649
2366	-----	-----	-----	-----	-----
2384	Not detected	Not detected	Not detected	Not detected	1.1930
2385	< 0.05	< 0.05	< 0.05	< 0.05	2.0441
2475	-----	-----	-----	-----	2.6143
2482	-----	-----	-----	-----	-----
2500	-----	-----	-----	-----	-----
2510	-----	-----	-----	-----	-----
2515	-----	-----	-----	-----	-----
2553	-----	-----	-----	-----	-----
2797	-----	-----	-----	-----	-----
2826	-----	-----	-----	-----	2.118
2897	-----	-----	-----	-----	-----
2901	-----	-----	-----	-----	-----
2925	-----	-----	-----	-----	-----
2976	Not Detected	Not Detected	Not Detected	Not Detected	N/A
3002	not detected	not detected	not detected	not detected	not determined
3017	not detected	not detected	not applicable	not applicable	not applicable
3024	Not Analyzed	Not Detected	Not Analyzed	Not Analyzed	1.9100
3028	<0.010	<0.010	<0.010	<0.010	>0.250
3122	nd	nd	nd	nd	1.3
3134	not analysed	not analysed	not analysed	not analysed	3.132
3172	< 0.1	< 0.1	< 0.1	< 0.1	0.9099
3182	Not analysed	Not analysed	Not analysed	Not analysed	Not analysed

sample #23721 Surface area, volume of simulant and final concentrations in mg/L

lab	surface area (dm²)	volume simulant (mL)	final concentration in simulant (mg/L)				
			Al	Ba	Co	Cu	Fe
339	2.08	350	0.165	1.666	0.606	0.001	0.005
362	2.0	330	-----	1.259	0.447	-----	-----
551	-----	-----	-----	-----	-----	-----	-----
2108	2	333	0.0350	1.2532	0.4167	not detected	not detected
2115	1	100	-----	8.479	3.22	-----	-----
2132	2.079	346	0.0955	0.9935	0.4823	0.001286	0.008727
2300	2.08	346.7	0.95	0.36	0.46	not detected	0.15
2353	2.0954	350	ND	1.620	0.627	ND	ND
2365	2.12	353	0.1030	1.4534	0.4762	<0.25	<5
2366	2.10	350	0.106	1.471	0.513	<0.25	<5.0
2384	0.3	50	<0.25	1.965	0.896	<0.25	<0.25
2385	2.0	330	0.154	1.01	0.454	<0.005	<0.005
2475	2.093	349	0.066	1.126	0.485	-----	0.015
2482	2.12	354	< 0,1	1.131	0.4169	< 0,5	< 1
2500	-----	-----	-----	-----	-----	-----	-----
2510	2.1042	750	0.0923	0.7313	0.3423	Below LOQ	Below LOQ
2515	2.0418	340	<0.1	1.7412	0.8361	<0.02	<0.02
2553	2.12	352.0	0.070	1.327	0.550	<0.040	0.049
2797	2.05	186	0.22439	3.1263	1.4689	not determined	not determined
2826	2.079	345	Not detected	1.46	0.69	Not detected	Not detected
2897	2.0	200	0.1766	2.7352	1.0902	not detected	not detected
2901	2.1	350	0.1182	1.8045	0.6336	<0.001	<0.05
2925	2.0384	200	0.149	2.295	0.880	ND	ND
2976	2.099	209.9	10.39 C	2 C	0.78 C	Not Detected	Not Detected
3002	1.99	328	0.113	1.575	0.572	not detected	not detected
3017	1.0	100.0	not applicable	1.1645	2.112	not detected	0.045
3024	2.0384	100.00	0.236819	3.838993	1.496336	0.041138	0.035974
3028	-----	-----	-----	-----	-----	-----	-----
3122	1	100	0.505	5.936	1.990	nd	nd
3134	-----	-----	-----	-----	-----	-----	-----
3172	2.1	350	< 0.2	1.34	0.70	< 1.0	< 10
3182	2.09	450.00	0.11	1.18	0.40	Not detected	Not detected

Lab 2976 first reported 259.75, 50.00 and 19.50 respectively

sample #23721 Surface area, volume of simulant and final concentrations in mg/L -- continued --

lab	Li	Mn	Ni	Zn
	final concentration in simulant (mg/L)			
339	0	0	0.001	0.011
362	-----	-----	-----	-----
551	-----	-----	-----	-----
2108	not detected	0.0083	not detected	not detected
2115	-----	-----	-----	0.118
2132	<0.1	0.000278	0.002457	0.006652
2300	not detected	not detected	0.03	0.08
2353	ND	ND	ND	ND
2365	<0.1	<0.1	<0.01	<0.5
2366	<0.10	<0.10	<0.01	<0.50
2384	<0.50	<0.25	<0.01	<0.50
2385	<0.005	<0.005	<0.005	0.023
2475	-----	-----	-----	0.018
2482	< 0,1	< 0,1	< 0,002	< 0,5
2500	-----	-----	-----	-----
2510	Below LOQ	Below LOQ	Below LOQ	0.1118
2515	<0.005	<0.005	<0.005	<0.02
2553	<0.010	<0.010	<0.010	0.052
2797	not determined	not determined	not determined	not determined
2826	Not detected	Not detected	Not detected	Not detected
2897	not detected	not detected	0.0025	not detected
2901	<0.001	<0.001	<0.001	<0.05
2925	ND	ND	ND	ND
2976	-----	Not Detected	Not Detected	Not Detected
3002	not detected	not detected	not detected	0.091
3017	not detected	not detected	not detected	not detected
3024	Not Detected	Not Detected	Not Detected	0.100672
3028	-----	-----	-----	-----
3122	nd	nd	nd	nd
3134	-----	-----	-----	-----
3172	< 0.1	< 0.1	< 0.01	< 0.5
3182	Not detected	Not detected	Not detected	Not detected

APPENDIX 4 Analytical details

Sample #23720

lab	accr. ISO 17025	sample cleaned prior to the migration step	simulant preheated	Equipment used	Sample sealed during test
339	Yes	No	Yes	Oven	Yes, with aluminum seal
362	---	---	---	---	---
551	---	---	---	---	---
2108	No	Yes, with lint-free cloth	Yes	Oven	Yes, with plastic wrap
2115	No	No	No	Incubator	yes, with watch glass
2132	Yes	Yes, with DI water	Yes	Oven	Yes, tested in an airtight container
2300	No	Yes, with lintfree tissue paper	Yes	Oven	Yes, with aluminum seal, with glass petridish
2353	No	No	Yes	Oven	Yes, covered by glass
2365	Yes	No	Yes	Oven	Yes, with aluminum seal
2366	---	---	---	---	---
2384	No	No	Yes	Oven	Yes, with aluminum seal
2385	Yes	No	Yes	Oven	Yes, with glass plate
2475	No	No	Yes	Oven	Yes, with aluminum seal
2482	---	---	---	---	---
2500	---	---	---	---	---
2510	---	---	---	---	---
2515	Yes	No	No	Oven	Yes, with aluminum seal
2553	---	---	---	---	---
2797	Yes	No	Yes	Incubator	Yes, tested in an airtight container
2826	Yes	No	Yes	Oven	Yes, with aluminum seal
2897	---	---	---	---	---
2901	---	---	---	---	---
2925	---	---	---	---	---
2976	No	Yes	Yes	Oven	Yes, with aluminum seal
3002	Yes	Yes,with water	Yes	Oven	Yes, tested in an airtight container
3017	No	Yes	Yes	---	No
3024	Yes	Yes, rinsed with purified water	No	Oven	Yes, sealed with a laboratory watch glass
3028	No	No	Yes	Oven	Yes, covered with glass plate
3122	No	No	Yes	Incubator	Yes, with aluminum seal
3134	No	No	Yes	Oven	Yes, aluminium foil and a glass lid was placed on top of the cup.
3172	No	No	Yes	Oven	Yes, with laboratory grade glass
3182	---	---	---	---	---

Sample #23721

lab	accr. ISO 17025	sample cleaned prior to the migration step	simulant preheated	Equipment used	Sample sealed during test
339	---	---	---	---	---
362	---	---	---	---	---
551	---	---	---	---	---
2108	No	Yes, with lint-free cloth	Yes	Oven	Yes, with plastic wrap Class beads were added, so that the plate was completely covered with simulant
2115	Yes	No	No	Incubator	No
2132	Yes	Yes, with DI water	Yes	Oven	Yes, tested in an airtight container
2300	No	Yes, with lint free cloth	Yes	Oven	Yes, sealed with reflux condense
2353	No	No	Yes	Oven	yes, covered by glass
2365	Yes	No	Yes	Oven	Yes, cling film
2366	Yes	No	Yes	Oven	Yes, tested in an airtight container
2384	Yes	No	Yes	Oven	Yes, tested in an airtight container
2385	Yes	No	Yes	Oven	Yes, with a glass-plate
2475	No	No	Yes	Oven	Yes, with aluminum seal
2482	No	Yes, with a lint-free cloth	Yes	Oven	Yes, with a watch glass
2500	---	---	---	---	---
2510	Yes	Yes, rinsed with UPW	Yes	Hot plate	Yes, sealed using a plastics autoclave bag and tape
2515	Yes	No	No	Oven	Yes, tested in an airtight container
2553	Yes	yes, using a cloth	yes	Oven	Yes, tested in an airtight container
2797	Yes	No	Yes	Oven	Yes, tested in an airtight container
2826	Yes	No	Yes	Oven	Yes, tested in an airtight container
2897	Yes	Yes, simple wash with water.	Yes	Oven	Yes, with a glass cover
2901	Yes	No	Yes	Oven	Yes, tested in an airtight container
2925	Yes	No	Yes	Oven	Yes, with a plastic film
2976	No	Yes	Yes	Oven	Yes, with aluminum seal
3002	Yes	Yes, with water	Yes	Oven	Yes, tested in an airtight container
3017	No	Yes	Yes		Yes, tested in an airtight container
3024	Yes	Yes, rinsed with purified water	No	Oven	Yes, sealed with a laboratory watch glass
3028	---	---	---	---	---
3122	Yes	No	Yes	Incubator	Yes, with cristal
3134	---	---	---	---	---
3172	---	---	---	---	---
3182	Yes	Yes, with tissue paper	Yes	Oven	Yes, with watch glass

APPENDIX 5

Number of participants per country

```
3 labs in  BRAZIL
1 lab in   BULGARIA
1 lab in   CROATIA
2 labs in  FRANCE
3 labs in  GERMANY
1 lab in   GREECE
3 labs in  HONG KONG
1 lab in   INDIA
1 lab in   IRELAND
1 lab in   ISRAEL
6 labs in  ITALY
1 lab in   MALAYSIA
3 labs in  P.R. of CHINA
1 lab in   SPAIN
1 lab in   SRI LANKA
1 lab in   THAILAND
2 labs in  VIETNAM
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APPENDIX 6

Abbreviations

C   = final test result after checking of first reported suspect test result
D(0.01)   = outlier in Dixon's outlier test
D(0.05)   = straggler in Dixon's outlier test
G(0.01)   = outlier in Grubbs' outlier test
G(0.05)   = straggler in Grubbs' outlier test
DG(0.01)   = outlier in Double Grubbs' outlier test
DG(0.05)   = straggler in Double Grubbs' outlier test
R(0.01)   = outlier in Rosner's outlier test
R(0.05)   = straggler in Rosner's outlier test
E   = calculation difference between reported test result and result calculated by iis
W   = test result withdrawn on request of participant
ex   = test result excluded from statistical evaluation
n.a.   = not applicable
n.e.   = not evaluated
n.d.   = not detected
fr.   = first reported
f+?   = possibly a false positive test result?
f-?   = possibly a false negative test result?

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