INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory No. 1004
accredited by ČIA according to ČSN EN ISO/IEC 17025:2018
L 1004

Testing laboratory * Calibration laboratory * Product certification body * Management systems certification body
Inspection body * Authorized body * Notified body

ACCREDITED LABORATORY TEST REPORT ref. No. 472115472-01

Client:	**Dalolinden AB** **VAT No. SE556526659901**
Address:	Silkesvägen 27, 33153 Värnamo, Sweden
Sample:	White plastic blade for spatula - see sample description on the page No. 2 of this document
Sample received on:	July 7, 2022
Report elaborated by:	Dipl. Ing. Andrea Ratiborská
Place and date of issue:	Zlín, August 3, 2022

Dipl. Ing. Jiří Samsonek, Ph.D.
Head of Accredited Testing Laboratory

Sample description and identification:

The client supplied for the testing sample of white plastic blade for spatula. The sample description is in the Table I.

Table No. I. – Sample description according to the client's declaration

ITC sample No.	Article name according to the client	Article composition according to the client
472115472/01	Spatula – white plastic blade	Material composition: Poly(ethylene/methylacrylate) ELVALOY™ AC 1913 ACRYLATE COPOLYMER DOW Europe GMBH Masterbatch: White MB MLL-10500-WN MB Normal White PELLD Addvanze

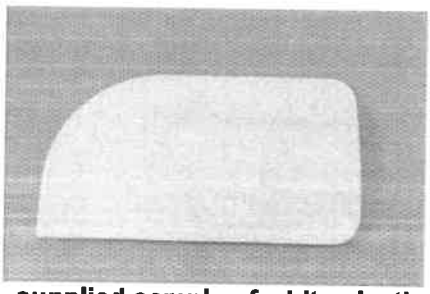

Fig. I – supplied sample of white plastic blade

Sampling method used:

The test sample was collected and supplied to the laboratory by the client. The laboratory is not responsible for this way of sampling.

Request:

Evaluation of the selected hygienic parameters of plastic articles according to the requirements of Commission Regulation 10/2011 as amended, Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

Testing method used:

The following tests were performed:

1.	Sensory analysis according to DIN 10955
2.	Overall migration into food simulants 3% acetic acid and 10% ethanol according to ČSN EN 1186–1 and ČSN EN 1186–3
3.	Overall migration into food simulant olive oil according to ČSN EN 1186–2
4.	Determination of specific migration of methyl-acrylate (PM/Ref. No. 11710, CAS No. 96-33-3) by GC-FID method according to IZP A-07-73
5.	Determination of specific migration of elements in the leachate by ICP-MS method according to IZP A-10-97
6.	Determination of specific migration of primary aromatic amines by LC-MS/MS method according to IZP A-95-28

Where internal test procedures (IZP) are specified in the test methods used, the annex to the Accreditation Certificate shall indicate for each internal procedure the links to the standards on which the internal test procedure is based.

Test conditions:

1.	Over boiled drinking water, 100cm² / 100ml, 70°C / 0,5h, multi-comparison paired test combined with scoring test according to DIN 10955 articles 11.6.3 c) and 12; 6 assessors
2.	The sample was cut, the migration was done by method of total immersion 100 cm²/100 ml, 70°C / 2 hours, 3% acetic acid, evaluation of the first, the second and the third migrations 100 cm²/100 ml, 70°C / 2 hours, 10% ethanol, evaluation of the first, the second and the third migrations
3.	The sample was cut, the migration was done by method of total immersion 100 cm²/100 ml, 70°C / 2 hours, olive oil, evaluation of the first, the second and the third migrations
4.	The sample was cut, the migration was done by method of total immersion 60 cm² / 100 ml, 70°C / 0,5 hour, 3% acetic acid 60 cm² / 100 ml, 70°C / 0,5 hour, 10% ethanol 60 cm² / 100 ml, 70°C / 0,5 hour, olive oil evaluation of the first, the second and the third migrations
5.	The sample was cut, the migration was done by method of total immersion 60 cm²/100 ml, 70°C / 0,5 hour, 3% acetic acid, evaluation of the first, the second and the third migrations
6.	The sample was cut, the migration was done by method of total immersion 60 cm²/100 ml, 70°C / 0,5 hour, 3% acetic acid, evaluation of the first, the second and the third migrations LC-MS/MS method: quantification of PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH (Regulation (EC) No. 1907/2006 of European Parliament and of Council), PAAs for which the specific migration limit in Annex I of Commission Regulation (EU) 10/2011 is stated and the selected other PAAs; detection of presence of other 25 PAAs

The laboratory is not responsible for information received from customer, which could have influence on the validity of the results. Further information required by the standard/standards and not given in this Test Report are available at a request at the Laboratory.

Testing laboratory:
All tests were performed in workplace no.: 1 - třída Tomáše Bati 299, Louky, 763 02 Zlín

Test results:

Table No. II. - Sensory analysis - Evaluation of off odour and off taste

Assessor	Unit [2]	Odour	Taste	Limit [1]	Evaluation [3]
Sample No. 472115472/01 – spatula – white plastic blade Over boiled drinking water, 70°C / 0,5 hour					
1	level	1	1	-	-
2	level	0	1	-	-
3	level	0	0	-	-
4	level	0	0	-	-
5	level	0	1	-	-
6	level	1	1	-	-
Median	**level**	**0**	**1**	**2,5**	**Pass**

Notes:

1) *According to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council the articles shall not cause deterioration in the organoleptic characteristics of food. The product is considered to be suitable for food contact if the levels 0 to 2,5 is achieved.*
2) *0 – No perceptible off-odour or off-taste*
   1 – Just perceptible off-odour or off-taste (off-odour and off-taste determination is very difficult)
   2 – Slightly perceptible off-odour or off-taste
   3 – Clearly perceptible off-odour or off-taste
   4 – Strong off-odour or off-taste
3) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

Table No. III. – Overall migration tests into aqueous simulants according to the requirements of Commission Regulation (EU) No. 10/2011

Parameter	Unit	Value obtained [1]				Analytical tolerance [2]	Limit [3]	Evaluation [4,5,6]
		1.	2.	3.	Mean value			
Sample No. 472115472/01 – spatula – white plastic blade								
3% acetic acid, 70°C / 2 hours								
1st migration	mg/dm²	1,0	1,3	< 1,0	[7]	1	-	-
2nd migration	mg/dm²	1,2	< 1,0	1,4	[7]	1	-	-
3rd migration	mg/dm²	< 1,0	< 1,0	< 1,0	**< 1,0**	1	10	Pass
10% ethanol, 70°C / 2 hours								
1st migration	mg/dm²	< 1,0	< 1,0	< 1,0	**< 1,0**	1	-	-
2nd migration	mg/dm²	< 1,0	< 1,0	< 1,0	**< 1,0**	1	-	-
3rd migration	mg/dm²	< 1,0	< 1,0	< 1,0	**< 1,0**	1	10	Pass

Notes:

1) *Symbol „<" means below LOQ (limit of quantification) of the analytical method*
2) *Analytical tolerance according to ČSN EN 1186-1, article 12.3 (for aqueous food simulants 1 mg/dm²)*
3) *Limit value according to the Commission Regulation 10/2011, as amended*
4) *According to ČSN EN 1186-1, article 12.3 – A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance (for aqueous food simulants 1 mg/dm²) should therefore be deemed to be in compliance*
5) *If the mean value of the second and the third migration tests does not exceed the mean value of the first test by an amount higher than the analytical tolerance (1 mg/dm² or 6 mg/kg for aqueous simulants), the subsequent test results are not considered as a migration increase – see ČSN EN 1186-1*
6) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*
7) *Mean value cannot be calculated because some of the obtained results were below LOQ*

Table No. IV. – Overall migration tests into olive oil according to the requirements of Commission Regulation (EU) No. 10/2011 – Part 1: Measured values

Parameter [1]	Unit	Value obtained [2]				
		1.	2.	3.	4.	Mean value
Sample No. 472115472/01 – spatula – white plastic blade						
overall migration to olive oil - M1 (70°C / 2 hours)	mg/dm²	< 2	< 2	< 2	< 2	**< 2**
overall migration to olive oil - M2 (70°C / 4 hours)	mg/dm²	< 2	< 2	< 2	< 2	**< 2**
overall migration to olive oil - M3 (70°C / 6 hours)	mg/dm²	< 2	< 2	< 2	< 2	**< 2**

Notes:

1) *M1 – is migration to olive oil, (70°C / 2 hours)*
   M2 – is migration to olive oil, (70°C / 4 hours)
   M3 – is migration to olive oil, (70°C / 6 hours)
2) *Symbol „<" means below LOQ (limit of quantification) of the analytical method*

Table No. V. – Overall migration tests into olive oil according to the requirements of Commission Regulation (EU) No. 10/2011 – Part 2: evaluation

Parameter	Unit	Value obtained [1]	Analytical tolerance [2]	Limit [3]	Evaluation [4,5,8]
Sample No. 472115472/01 – spatula – white plastic blade					
overall migration to olive oil – first migration	mg/dm²	< 2	3	-	-
overall migration to olive oil – second migration [6]	mg/dm²	< 2	3	-	-
overall migration to olive oil – third migration [7]	mg/dm²	< 2	3	10	Pass

Notes:

1) *Symbol „<" means below LOQ (limit of quantification) of the analytical method*
2) *Analytical tolerance according to ČSN EN 1186-1, article 12.3 (for fatty food simulants 3 mg/dm²)*
3) *Limit value according to the Commission Regulation 10/2011, as amended*
4) *According to ČSN EN 1186-1, article 12.3 – A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance (for fatty food simulants 3 mg/dm²) should therefore be deemed to be in compliance*
5) *If the mean value of the second and the third migration tests does not exceed the mean value of the first test by an amount higher than the analytical tolerance (3 mg/dm² or 20 mg/kg for fatty food simulants and substitute fatty food simulants), the subsequent test results are not considered as a migration increase – see ČSN EN 1186-1*
6) *Second subsequent migration calculated as M2-M1*
   (M1 – is migration to olive oil, 70°C, 2 hours, M2 – is migration to olive oil, 70°C, 4 hours)
7) *Third subsequent migration, calculated as M3-M2*
   (M2 – is migration to olive oil, 70°C, 4 hours, M3 – is migration to olive oil, 70°C, 6 hours)
8) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

Table No. VI. - Specific migration tests according to the requirements of Commission Regulation (EU) No. 10/2011

Parameter	Unit	Value obtained [1,2]	Uncertainty	Limit [3,4]	Evaluation [5,6]
Specific migration of methyl-acrylate (PM/Ref. No. 11710, CAS No. 96-33-3)					
Sample No. 472115472/01 – spatula – white plastic blade					
3% acetic acid, 70°C / 0,5 hour					
1st migration	mg/kg	< 0,5	-	-	-
2nd migration	mg/kg	< 0,5	-	-	-
3rd migration	mg/kg	< 0,5	-	6	Pass
10% ethanol, 70°C / 0,5 hour					
1st migration	mg/kg	< 0,5	-	-	-
2nd migration	mg/kg	< 0,5	-	-	-
3rd migration	mg/kg	< 0,5	-	6	Pass
Olive oil, 70°C / 0,5 hour					
1st migration	mg/kg	< 0,5	-	-	-
2nd migration	mg/kg	< 0,5	-	-	-
3rd migration	mg/kg	< 0,5	-	6	Pass

Notes:

1) *Symbol "<" means less than the limit of detection of the analytical method*
2) *Results are expressed as acrylic acid*
3) *Sum of FCM substances No. 70, 147, 176, 218, 323, 235, 365, 371, 380, 425, 446, 448, 456 and 636 expressed as acrylic acid*
4) *Limit values according to Commission Regulation EU 10/2011 as amended*
5) *Compliance with Annex V; Chapter 2, article 2.1.6 is based on the level of the migration found in the third test and the stability of the sample from the first to the third migration test (the migration level including the measurement uncertainty shall not increase from the first migration test to the third migration test)*
6) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

Table No. VII. - Test result of specific migration of primary aromatic amines (PAAs) - Annex II (10/2011)

Primary aromatic amine (PAA)	CAS No.	Unit [1]	Test result [2,3]			Limit [4]
			1st migration	2nd migration	3rd migration	
PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH						
Sample No. 472115472/01 – spatula – white plastic blade **Specific migration into 3% acetic acid, 70°C / 0,5 hour**						
4-Amino-biphenyle	92-67-1	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
Benzidine	92-87-5	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
4-Chlor-o-toluidine	95-69-2	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
2-Naphthylamine	91-59-8	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
o-Aminoazotoluene	97-56-3	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
2-Amino-4-nitro-toluene	99-55-8	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
p-Chlor -aniline	106-47-8	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
2,4-Diamino-anisole	615-05-4	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
4,4'-Diamino-diphenylmethane	101-77-9	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
3,3'-Dichlor-benzidine	91-94-1	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
3,3'-Dimethoxy-benzidine	119-90-4	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
3,3'-Dimethyl-benzidine	119-93-7	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
p-Keresidine	120-71-8	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
4,4'-Methylen-bis(2-chloraniline)	101-14-4	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
4,4'-Oxy-dianiline	101-80-4	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
4,4'-Thio-dianiline	139-65-1	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
o-Toluidine	95-53-4	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
2,4-Toluenediamine	95-80-7	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
2,4,5-Trimethyl-aniline	137-17-7	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
o-Anisidine	90-04-0	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
o-Aminoazobenzene	60-09-3	mg/kg	< 0,002	< 0,002	< 0,002	N.D.
Evaluation			**Pass [5]**			

Notes:

1) *Expressed as mg of the substance per kg of food simulant*
2) *Symbol „<" means less than limit of detection of the analytical method*
3) *The test results of the first, the second and the third subsequent migrations are reported*
4) *Limit values according to Commission Regulation EU 10/2011 as amended*
5) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

REACH = Regulation (EC) No. 1907/2006 of European Parliament and of Council
N.D. = not detectable; limit of detection 0.002 mg/kg

Table No. VIII. - Test result of specific migration of primary aromatic amines (PAAs) - Annex II (10/2011)

Primary aromatic amine (PAA)	CAS No.	Unit [1]	Test result [2]			Limit [3]
			1st migration	2nd migration	3rd migration	
Other PAAs (not listed in REACH)						
Sample No. 472115472/01 – spatula – white plastic blade **Specific migration into 3% acetic acid, 70°C / 0,5 hour**						
Screening for others	[4]	-	No PAA detected [5]	No PAA detected [5]	No PAA detected [5]	-
Sum of detected PAAs		mg/kg	-	-	-	0,01
Evaluation		**Pass [6]**				

Notes:

1) *Expressed as mg of the substance per kg of food simulant*
2) *The test results of first, second and third subsequent migrations are reported*
3) *Limit values according to Commission Regulation EU 10/2011 as amended*
4) *These PAAs were screened – CAS No. 95-68-1, CAS No. 87-62-7, CAS No. 2243-62-1, CAS No. 62-53-3, CAS No. 95-51-2, CAS No. 108-42-9, CAS No. 106-49-0, CAS No. 106-50-3, CAS No. 823-40-5, CAS No. 121-69-7, CAS No. 6582-52-1, CAS No. 1208-52-2, CAS No. 6358-64-1, CAS No. 95-82-9, CAS No. 94-70-2, CAS No. 2835-68-9, CAS No. 81-16-3, CAS No. 88-44-8, CAS No. 49564-57-0, CAS No. 95-23-8, CAS No. 132-32-1, CAS No. 95-54-5, CAS No. 67014-36-2, CAS No. 156-43-4, CAS No. 90-41-5*
5) *LOD (limit of detection) of individual PAA is 0,005 mg/kg*
6) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

REACH = Regulation (EC) No. 1907/2006 of European Parliament and of Council

Table No. IX. - Test result of specific migration of primary aromatic amines (PAAs) - Annex I (10/2011)

Primary aromatic amine (PAA)	CAS No.	Unit [1]	Test result [2,3]			Limit [4]
			1st migration	2nd migration	3rd migration	
Sample No. 472115472/01 – spatula – white plastic blade **Specific migration into 3% acetic acid, 70°C / 0,5 hour**						
Bis(4-aminophenyl)sulphone	80-08-0	mg/kg	< 0,005	< 0,005	< 0,005	5
2-Aminobenzamide	88-68-6	mg/kg	< 0,005	< 0,005	< 0,005	0,05
1,3-Phenylenediamine	108-45-2	mg/kg	< 0,002	< 0,002	< 0,002	0,002
4,4'-methylenebis(3-chloro-2,6-diethylaniline)	106246-33-7	mg/kg	< 0,005	< 0,005	< 0,005	0,05
Evaluation		**Pass [5]**				

Notes:

1) *Expressed as mg of the substance per kg of food simulant*
2) *Symbol „<" means less than limit of detection of the analytical method*
3) *The test results of the first, the second and the third subsequent migrations are reported*
4) *Limit values according to Commission Regulation EU 10/2011 as amended*
5) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

Table No. X. – Specific migration of metals according to the Annex II of Commission Regulation 10/2011

Element	Unit [1]	Test results [2,3]			Limit [4]	Evaluation [5,6]
		1st migration	2nd migration	3rd migration		
Sample No. 472115472/01 – spatula – white plastic blade Specific migration into 3% acetic acid, 70°C / 0,5 hour						
Barium Ba	mg/kg	< 0,05	< 0,05	< 0,05	1	Pass
Cobalt Co	mg/kg	< 0,005	< 0,005	< 0,005	0,05	Pass
Copper Cu	mg/kg	< 0,05	< 0,05	< 0,05	5	Pass
Iron Fe	mg/kg	< 0,10	< 0,10	< 0,10	48	Pass
Lithium Li	mg/kg	< 0,01	< 0,01	< 0,01	0,6	Pass
Manganese Mn	mg/kg	< 0,01	< 0,01	< 0,01	0,6	Pass
Zinc Zn	mg/kg	< 0,10	< 0,10	< 0,10	5	Pass
Aluminum Al	mg/kg	< 0,10	< 0,10	< 0,10	1	Pass
Nickel Ni	mg/kg	< 0,01	< 0,01	< 0,01	0,02	Pass
Antimony Sb	mg/kg	< 0,005	< 0,005	< 0,005	0,04	Pass
Europium Eu	mg/kg	< 0,001	< 0,001	< 0,001	0,05	Pass
Gadolinium Gd	mg/kg	< 0,001	< 0,001	< 0,001	0,05	Pass
Lanthanum La	mg/kg	< 0,001	< 0,001	< 0,001	0,05	Pass
Terbium Tb	mg/kg	< 0,001	< 0,001	< 0,001	0,05	Pass
Sum of Lanthanides	mg/kg	< 0,004	< 0,004	< 0,004	0,05	Pass
Arsenic As	mg/kg	< 0,001	< 0,001	< 0,001	N.D. (0,01)	Pass
Cadmium Cd	mg/kg	< 0,001	< 0,001	< 0,001	N.D. (0,002)	Pass
Chromium Cr	mg/kg	< 0,005	< 0,005	< 0,005	N.D. (0,01)	Pass
Lead Pb	mg/kg	< 0,005	< 0,005	< 0,005	N.D. (0,01)	Pass
Mercury Hg	mg/kg	< 0,002	< 0,002	< 0,002	N.D. (0,01)	Pass

Notes:

1) *Expressed as mg of the element per kg of food simulant for migration ratio 6 dm^2/kg*
2) *Symbol „<" means less than limit of detection of the analytical method*
3) *The test results of the first, the second and the third subsequent migration tests are reported*
4) *Limit values according to Commission Regulation 10/2011 as amended. N.D. = not detectable; for limit of detection see the value in brackets. The test result of the third test is compared to the limit value. For "N.D." limit all test results are compared to the limit.*
5) *Compliance with Annex V; Chapter 2, article 2.1.6 is based on the level of the migration found in the third test and the stability of the sample from the first to the third migration test (the migration level including the measurement uncertainty shall not increase from the first migration test to the third migration test)*
6) *In accordance with ILAC-G08 - Binary statement for the simple acceptance rule (measurement uncertainty is not taken into consideration for the evaluation)*

Evaluation carried out by:
Dipl. Ing. Andrea Ratiborská

Dipl. Ing. Daniel Vít
Head of the laboratory of analytical chemistry and microbiology

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	980	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	10% Ethanol
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Ethanol 10%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.390E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	9.800E-01	-

2.5 Substances

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE

CAS number :	0002082-79-3
FCM Number :	433
Molecular weight :	5.309E+02
Density :	9.290E-01
POW :	1.341E+01

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.400E-01
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

Compliance Certificate

3. Migration results

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR Final Concentration : 1.459E-04 (mg/kg)

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Compliance Certificate

4. Repeated use

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR

Concentration after cycle 1	**4.595E-04**	**(mg/kg)**
Concentration after cycle 2	**1.901E-04**	**(mg/kg)**
Concentration after cycle 3	**1.459E-04**	**(mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	1000	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	3% Acetic Acid
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Acetic acid 3%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.390E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	1.000E+00	-

Compliance Certificate

2.5 Substances

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE

CAS number :	0002082-79-3
FCM Number :	433
Molecular weight :	5.309E+02
Density :	9.290E-01
POW :	1.341E+01

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.400E-01
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

Compliance Certificate

3. Migration results

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR Final Concentration : 1.429E-04 (mg/kg)

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR

Concentration after cycle 1	**4.503E-04**	**(mg/kg)**
Concentration after cycle 2	**1.863E-04**	**(mg/kg)**
Concentration after cycle 3	**1.429E-04**	**(mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	800	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	95% Ethanol
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Ethanol 95%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.390E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	8.000E-01	-

Compliance Certificate

2.5 Substances

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE

CAS number :	0002082-79-3
FCM Number :	433
Molecular weight :	5.309E+02
Density :	9.290E-01
POW :	1.341E+01

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.400E-01
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

Compliance Certificate

3. Migration results

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR Final Concentration : 1.787E-04 (mg/kg)

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR

Concentration after cycle 1	**5.628E-04 (mg/kg)**
Concentration after cycle 2	**2.329E-04 (mg/kg)**
Concentration after cycle 3	**1.787E-04 (mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	800	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

Compliance Certificate

2.3 Article

Article :	Iso-octane
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : iso-Octane

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.390E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	8.000E-01	-

Compliance Certificate

2.5 Substances

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE

CAS number :	0002082-79-3
FCM Number :	433
Molecular weight :	5.309E+02
Density :	9.290E-01
POW :	1.341E+01

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.400E-01
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

SML v 6.51

Compliance Certificate

3. Migration results

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR Final Concentration : 1.787E-04 (mg/kg)

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR

Concentration after cycle 1	**5.628E-04 (mg/kg)**
Concentration after cycle 2	**2.329E-04 (mg/kg)**
Concentration after cycle 3	**1.787E-04 (mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	910	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	Olive Oil
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Olive oil

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.390E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	9.100E-01	-

Compliance Certificate

2.5 Substances

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PROPIONATE

CAS number :	0002082-79-3
FCM Number :	433
Molecular weight :	5.309E+02
Density :	9.290E-01
POW :	1.341E+01

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.400E-01
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

SML v 6.51

Compliance Certificate

3. Migration results

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR Final Concentration : 1.571E-04 (mg/kg)

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

OCTADECYL 3-(3,5-DI-tert-BUTYL-4-HYDROXYPHENYL) PR

Concentration after cycle 1	**4.948E-04**	**(mg/kg)**
Concentration after cycle 2	**2.048E-04**	**(mg/kg)**
Concentration after cycle 3	**1.571E-04**	**(mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	800	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

Compliance Certificate

2.3 Article

Article :	Iso-octane
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : iso-Octane

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.400E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	8.000E-01	-

Compliance Certificate

2.5 Substances

1,1,1-Trimethylolpropane

CAS number :	0000077-99-6
FCM Number :	141
Molecular weight :	1.342E+02
Density :	6.000E-01
POW :	-1.480E+00

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.025E+00
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

Compliance Certificate

3. Migration results

1,1,1-Trimethylolpropane **Final Concentration :** **1.509E-03 (mg/kg)**

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Compliance Certificate

4. Repeated use

1,1,1-Trimethylolpropane

Concentration after cycle 1	**4.754E-03**	**(mg/kg)**
Concentration after cycle 2	**1.967E-03**	**(mg/kg)**
Concentration after cycle 3	**1.509E-03**	**(mg/kg)**

SML v 6.51

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	800	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	95% Ethanol
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Ethanol 95%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.400E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	8.000E-01	-

2.5 Substances

1,1,1-Trimethylolpropane

CAS number :	0000077-99-6
FCM Number :	141
Molecular weight :	1.342E+02
Density :	6.000E-01
POW :	-1.480E+00

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.025E+00
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

SML v 6.51

Compliance Certificate

3. Migration results

1,1,1-Trimethylolpropane **Final Concentration :** **1.509E-03 (mg/kg)**

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Compliance Certificate

4. Repeated use

1,1,1-Trimethylolpropane

Concentration after cycle 1	**4.754E-03**	**(mg/kg)**
Concentration after cycle 2	**1.967E-03**	**(mg/kg)**
Concentration after cycle 3	**1.509E-03**	**(mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	910	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	Olive Oil
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Olive oil

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.400E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	9.100E-01	-

2.5 Substances

1,1,1-Trimethylolpropane

CAS number :	0000077-99-6
FCM Number :	141
Molecular weight :	1.342E+02
Density :	6.000E-01
POW :	-1.480E+00

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.025E+00
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

SML v 6.51

Compliance Certificate

3. Migration results

1,1,1-Trimethylolpropane **Final Concentration :** **1.327E-03 (mg/kg)**

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

1,1,1-Trimethylolpropane

Concentration after cycle 1	**4.179E-03**	**(mg/kg)**
Concentration after cycle 2	**1.730E-03**	**(mg/kg)**
Concentration after cycle 3	**1.327E-03**	**(mg/kg)**

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10 Height (cm): 10 Length (cm): 10
Volume (cm3) :	1000	
Mass (g):	980	
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	10% Ethanol
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Ethanol 10%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.400E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	9.800E-01	-

2.5 Substances

1,1,1-Trimethylolpropane

CAS number :	0000077-99-6
FCM Number :	141
Molecular weight :	1.342E+02
Density :	6.000E-01
POW :	-1.480E+00

Initial concentration

Layer	Concentration (mg/kg)
Layer 1	2.025E+00
Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

Compliance Certificate

3. Migration results

1,1,1-Trimethylolpropane **Final Concentration :** **1.232E-03 (mg/kg)**

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

4. Repeated use

1,1,1-Trimethylolpropane

Concentration after cycle 1	**3.881E-03**	**(mg/kg)**
Concentration after cycle 2	**1.606E-03**	**(mg/kg)**
Concentration after cycle 3	**1.232E-03**	**(mg/kg)**

SML v 6.51

Compliance Certificate

Estimation of specific migration for monomers and additives by migration modelling from food contact materials.

1. Aim

Estimation of specific migration by generally recognised diffusion models based on scientific evidence (migration modelling) according to Chapter 2.2.3 in Annex V of Regulation (EU) No 10/2011 from a monolayer or multilayer plastic food contact material.

2. Information / Inputs

For migration modelling the following data (inputs) were used:

Cp ,0	Initial concentration of the migrant in the polymer
Tp	Thickness of the polymer
Pp	Density of the polymer
Dp	Diffusion coefficient of the migrant in the polymer
Vf	Volume of the contact medium
Pf	Density of the contact medium
Mf	Mass of contact medium
Kp,f	Partition coefficient of the migrant between polymer and contact medium
A	Contact area
t	Contact time
T	Contact temperature

2.1 Package geometry

Type :	rectangular	Width (cm): 10
Volume (cm3) :	1000	Height (cm): 10
Mass (g):	1000	Length (cm): 10
Contact surface (cm2):	600	

2.2 Time / Temperature conditions

Duration :	6 hour(s)
Temperature :	Repeated use (1 cycles, 6h) 70 °C, 2h 70 °C, 2h 70 °C, 2h

2.3 Article

Article :	3% Acetic Acid
Layers :	2
Chemicals :	1
Contact medium :	Contact Medium : Acetic acid 3%

2.4 Structure

N°	Layer name	Sim. type	Thickn.(um)	Density(g/cm3)	Polymer
0	Layer 1	Upper limit	3.500E+03	9.400E-01	ETHYLENE-METHYL ACRYLATE COPOLYMI
1	Contact Medium	Upper limit	1.667E+04	1.000E+00	-

Compliance Certificate

2.5 Substances

1,1,1-Trimethylolpropane

CAS number :	0000077-99-6
FCM Number :	141
Molecular weight :	1.342E+02
Density :	6.000E-01
POW :	-1.480E+00

Initial concentration

Layer	Concentration (mg/kg)
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Contact Medium	0.000E+00

Partition coef.

Layer	Type	Partition
Layer 1	-	-
Contact Medium	Van't Hoff based	3.446E-12

Diffusion coef

Layer	Type	Diffusion (cm2/s)
Layer 1	Arrhenius based	1.207E-09
Contact Medium	Arrhenius based	1.207E-09

SML v 6.51

Compliance Certificate

3. Migration results

1,1,1-Trimethylolpropane **Final Concentration :** **1.207E-03 (mg/kg)**

Regulation reference : SR 817.023.21 (2016)

Region : Switzerland

Date : 16.12.2016 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : 2002/72/EC

Region : European Union

Date : 06.08.2002 Type : Directive

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Regulation reference : (EU) No 10/2011 amended up to (EU) No 2018/831

Region : European Union

Date : 05.06.2018 Type : Regulation

Application : FCM

Type	sml	qm	qma	dl
Limit	6	-	-	-
Compliance	Passed	N/A	N/A	N/A

Compliance Certificate

4. Repeated use

1,1,1-Trimethylolpropane

Concentration after cycle 1	**3.803E-03**	**(mg/kg)**
Concentration after cycle 2	**1.574E-03**	**(mg/kg)**
Concentration after cycle 3	**1.207E-03**	**(mg/kg)**