

DIVISIONE: **FOOD PACKAGING MATERIALS** LABORATORIO: **FOOD CONTACTS**  
 DIVISION: **FOOD PACKAGING MATERIALS** LABORATORY:

<b>RAPPORTO DI PROVA</b> <i>(Test Report)</i>		Pag. 1 di/of
		pag. 12
N°	0240\FPM\FDC\11_10	Data: 12/04/2011 Date:

 IDENTIFICAZIONE E DESCRIZIONE DEL CAMPIONE:  
 SPECIMEN DESCRIPTION:  

**PTFE PLATE G405**


 DATI IDENTIFICATIVI DEL CLIENTE:  
 CLIENT:  

**GUARNIFLON SPA**  
 VIA T.TASSO, 12  
 24060 TAGLIUNODI CASTELLI CALEPIO (BG)

 NORMA DI RIFERIMENTO:  
 REFERENCE STANDARD:  
 D.M. 34 dated 21.3.73 O.S. of the Official Gazette n. 104 dated 20 of April 1973, D.M. 220 dated 26/04/93 O.S. GU n° 162 dated 13/07/93, Annex of Decree 338 dated 22/07/98 GU n° 228 dated 30/09/98, D.M. 299 dated 22/12/05 GU n° 37 dated 14/02/06; European Directives: 82/711/EEC GUCEE L 297 dated 23/10/82, 85/572/EEC GUCEE L 372 dated 31/12/1985, 93/8/EEC GU L90 dated 14/04/1993, 97/48/EC GUCE L 222 dated 12/8/97, 2002/72/EC GUCE L 220 dated 15/8/02, 2004/19/EC GUCE L 71 dated 10/3/04, 2005/79/EC GUCE L 302 dated 19/11/05, 2007/19/EC GUCE L 91 dated 31/3/07 and Dir. 2008/39/EC GUCE L 63 dated 07/03/2008 and Regulation 975/2009/EC GUCE L 274 dated 20/10/2009. Regulations 1935/2004/EC GUCE L 338 dated 13/11/04 and 1895/2005/EC GUCE L 302 dated 19/11/2005.UNI EN 1186 1+15:2003. FDA vol. 21, Cap. 177,1550. FDA vol. 21, Cap. 175.300

DISTRIBUZIONE ESTERNA: OUTSIDE DISTRIBUTION: <p style="text-align: center;"><b>GUARNIFLON SPA</b>  <b>Sig. Nocera</b></p>	DISTRIBUZIONE INTERNA: INSIDE DISTRIBUTION: <p style="text-align: center;">Copy to Division Head</p>
---	--

 ENTE DI ACCREDITAMENTO:  
 ACCREDITATION BODY:  



**ACCREDIA**  
L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N°0006  
 Signatory of EA, IAF and ILAC  
 Mutual Recognition Agreements

Mod. 37 - Rev. 7 - Società a Socio Unico soggetto ad attività di direzione e coordinamento di IMQ spa

## GENERALITIES

- Sample receiving date: 02/03/2011
- Analysis start date: 02/03/2011
- Analysis end date: 31/03/2011
- Deviation from test methods: NO

## SAMPLE DESCRIPTION

### PTFE PLATE G405

## SAMPLING

The initial sampling has been done by the customer.  
The sampling for the test has been done drawing casually part of the sample in our possession.

## DECLARATION

The test results of the present report are related exclusively to the tested sample.  
The present test report cannot be partially reproduced without the authorization of CSI managing Director.

(\*) The uncertainties are estimated as extended uncertainty obtained multiplying the standard uncertainty by the coverage factor k corresponding to a confidence level of about 95%. Normally, this factor = 2.

(\*) Test not under ACCREDIA accreditation.

## PERFORMED DETERMINATIONS

### 1) DETERMINATION OF THE OVERALL MIGRATION

Verification of the suitability of articles and materials to be employed in contact with foodstuffs, according to DM n. 34 dated 21.3.73 (O.S. of the Official Gazette n. 104 dated 20 of April 1973) and subsequent revisions and updatings; European Directives 82/711/EEC, 85/572/EEC, 93/8/EEC, 97/48/EC, 2002/72/EC, 2004/19/EC, 2005/79/EC and 2007/19; Reg. EC n. 1935/2004.

UNI EN 1186 1-15:2003

Food simulant	Contact condition
Acetic acid 3% W/v in aqueous solution	10 days at 40°C
Ethanol 50% v/v in aqueous solution	10 days at 40°C
Rectified olive oil	10 days at 40°C

The samples have been tested using **TOTAL IMMERSION** procedure.

The ratio between exposed sample surface (dm<sup>2</sup>) and simulant volume (dL) is equal to 1, the directive the ratio has to be included from 0,5 to 2.

LOD (limit of detection): 1 mg/dm<sup>2</sup>.

## 2) DETERMINATION OF THE COLOURING MIGRATION

Determination of the colouring migration agents from the tested material into liquids obtained from migration test by spectrophotometric analysis in the spectral range 400 - 750 nm, with 10 cm optical path cell for the aqueous simulants and 1 cm for oily simulant according to DM n. 34 dated 21.3.73 (O.S. of the Official Gazette n. 104 dated 20 of April 1973) and subsequent updating.

Minimum value: 95% Transmittance (T%)

## 3) QUANTITATIVE DETERMINATION OF PRIMARY AROMATIC AMINES: METHOD L.00.00-6 (LFGB § 64)

The procedure used to quantify the primary aromatic amines was a spectrophotometer method, based on the colour complex formed by a diazotization and a coupletization reaction. The solution was further concentrated and eluted on a solid phase column. The final solution was photometrically detected at 550 nm (Method Amtliche Sammiung von Untersuchungsverfahren § 35 BGVV / § 64 LFGB, L.00.00-6 del 1995 agg. 2002)

An external calibration curve detected at 550 nm was used to quantify the primary aromatic amines. An aniline standard solution 0, 0.5, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0 µg in acetic acid 3% was detected.

LOD: 0.2 µg /100 ml or LOD: 0.002 mg/kg or LOD: 0.0003\* mg/dmq (\*the limit is originally expressed in mg/kg it is possible to convert the measure unit by dividend for the factor 6 to express them in mg/dmq.)

## 4) DETERMINATION OF THE SPECIFIC MIGRATION OF TETRAFLUOROETHYLENE(\*\*)

The determination of tetrafluoroethylene specific migration in the three previously described simulants has been carried out after conditioning at the previously described conditions by Head space Analysis using a GC-MS (HO 7694/HP6890-5973).

Quantification has been obtained using a external calibration of tetrafluoroethylene in previously described simulants.

L.O.D.: 0.05 mg/kg

SML: 0.05 mg/kg

## 5) OLFACTORY ORGANOLEPTIC TEST ACCORDING TO UNI 10192 (\*\*)

The olfactory scoring test is a evaluation of the odor, measured with a 5 point scale. Each judge is asked to smell a series of coded dark flasks containing the samples. They are then asked to give a mark to each flask:

- 0: no perceivable smell
- 1: little perceivable smell, very difficult to define;
- 2: weak but identifiable smell;
- 3: strong smell;
- 4: very strong smell

The final result is expressed with the average value of the scores given by each judge, coupled with the standard deviation.

Testing conditions:

- time of conditioning : 18 hours
- temperature of conditioning :  $55 \pm 1$  °C
- n° judges : 8
- quantity of sample: 1,5 dm<sup>2</sup>
- volume of jar: 500 ml

A potential organoleptic impact is to be acknowledged to the sample if the average score plus one time the standard deviation is  $\geq$  than 3.

## 6) VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 177.1550.

### 6.1) Total extractives

Distilled water:	<b>2 hours at reflux temperature</b>
Ethanol 50 % v/v	<b>2 hours at reflux temperature</b>
n-heptane:	<b>2 hours at reflux temperature</b>
Ethyl-acetate:	<b>2 hours at reflux temperature</b>

### 6.2) Fluoride extractives

The determination of the fluoride in the following simulants: distilled water, ethanol 50% v/v, n-heptane and ethyl-acetate by IC (Ion Chromatography) technique with METROHM Separation Center 820 instrument.

Coloumn : Metrosep A Supp 5-520  
Eluent: Na<sub>2</sub>CO<sub>3</sub> (3.2 mmol/l) / NaHCO<sub>3</sub> (1.0 mmol/l)  
Flux: 0.7 ml/min  
Injection volume: 1ul

### 6.3) Infrared identification of coating

Identification of the nature of the sample by surface reflection analysis with FTIR Perkin Elmer SPECTRUM ONE series equipped with Universal ATR accessory (resolution 4 cm-1, reflection on single crystal ZnSe, 4 scans additive).

## 7) VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 175.300

Distilled water	<b>2 hours at 250F</b>
Ethanol 8% v/v	<b>2 hours at 150F</b>
n-Heptane	<b>2 hours at 150F</b>

## RESULTS

### 1) DETERMINATION OF THE OVERALL MIGRATION

<b>PTFE G405 Plate</b>			
Food Simulant: <b>Acetic acid 3% w/v in aqueous solution</b>			
Contact condition: <b>10 days at 40°C</b>			
Measured unit: <b>mg/dm<sup>2</sup></b>			
Measured value	Average value	Extended uncertainty(*)	Limit Value (according to 2002/72/EC)
24,8	20,3	7,0	10
19,1			
18,1			

<b>PTFE G405 Plate</b>			
Food Simulant: <b>Ethanol 50%</b>			
Contact condition: <b>10 days at 40°C</b>			
Measured unit: <b>mg/dm<sup>2</sup></b>			
Measured value	Average value	Extended uncertainty(*)	Limit Value (according to 2002/72/EC)
2,4	2,5	0,2	10
2,4			
2,6			

<b>PTFE G405 Plate</b>						
Food simulant: <b>Rectified olive oil</b>						
Contact condition: <b>10 days at 40°C</b>						
Measured unit: <b>mg/dm<sup>2</sup></b>						
measured value	average value	Extended uncertainty (1)	To be subtracted from replications average if >2	Replications average – volatiles average	Extended uncertainty (*)	limit value (according to 2002/72/EC)
< 1	< 1	---	< 2	< 1	---	10
< 1						
< 1						

**2) DETERMINATION OF THE COLOURING MIGRATION**

<b>PTFE G405 Plate</b>			
Food simulant: <b>Acetic acid in aqueous solution 3% w/v</b>			
Contact condition: <b>10 days at 40°C</b>			
Optical path: <b>10 cm</b>			
Measured unit: <b>T%</b>			
<b>Measured value</b>	<b>Average value</b>	<b>Extended uncertainty (***)</b>	<b>limit value (according to DM 21/03/73)</b>
99.8	99.8	0.5	≥ 95
99.8			
99.8			

<b>PTFE G405 Plate</b>			
Food simulant: <b>Ethanol 50% v/v</b>			
Contact condition: <b>10 days at 40°C</b>			
Optical path: <b>10 cm</b>			
Measured unit: <b>T%</b>			
<b>Measured value</b>	<b>Average value</b>	<b>Extended uncertainty (***)</b>	<b>limit value (according to DM 21/03/73)</b>
98.5	98.4	0.5	≥ 95
98.4			
98.5			

<b>PTFE G405 Plate</b>			
Food simulant: <b>Sunflower oil</b>			
Contact condition: <b>10 days at 40°C</b>			
Optical path: <b>1 cm</b>			
Measured unit: <b>T%</b>			
<b>Measured value</b>	<b>Average value</b>	<b>Extended uncertainty (***)</b>	<b>limit value (according to DM 21/03/73)</b>
98.5	98.5	0.5	≥ 95
98.9			
98.5			

(\*\*\*) for this variable the third paragraph of **DECLARATIONS** is not applicable

**3) QUANTITATIVE DETERMINATION OF PRIMARY AROMATIC AMINES: METHOD L.00.00-6 (LFGB § 64)**

<b>PTFE G405 Plate</b> Simulant: <b>Acetic acid 3 % w/v in aqueous solution</b> Contact condition: <b>2 hours at 70°C</b>			
Measured value	Average value	Standard deviation <sup>1)</sup>	Limit Value (according to 2007/19/EC)
<0.002 mg/Kg	<0.002 mg/Kg	--	0.01 mg/Kg
<0.002 mg/Kg			
<0.002 mg/Kg			

**4) DETERMINATION OF THE SPECIFIC MIGRATION OF TETRAFLUOROETHYLENE (\*)**

<b>PTFE G405 Plate</b> Food Simulant: <b>Acetic acid 3% w/v in aqueous solution</b> Contact condition: <b>10 days at 40°C</b> Measured unit: <b>mg/kg</b>			
Measured value	Average value	Extended uncertainty <sup>(*)</sup>	Limit Value (according to 2002/72/EC)
< 0.05	< 0.05	---	0.05
< 0.05			
< 0.05			



<b>PTFE G405 Plate</b>			
Food Simulant: <b>Ethanol 50%</b>			
Contact condition: <b>10 days at 40°C</b>			
Measured unit: <b>mg/kg</b>			
Measured value	Average value	Extended uncertainty <sup>(1)</sup>	Limit Value (according to 2002/72/EC)
< 0.05	< 0.05	---	0.05
< 0.05			
< 0.05			

<b>PTFE G405 Plate</b>			
Food simulant: <b>Rectified olive oil</b>			
Contact condition: <b>10 days at 40°C</b>			
Measured unit: <b>mg/kg</b>			
Measured value	Average value	Extended uncertainty <sup>(*)</sup>	Limit Value (according to 2002/72/EC)
< 0.05	< 0.05	---	0.05
< 0.05			
< 0.05			

### 5) OLFACTORY ORGANOLEPTIC TEST ACCORDING TO UNI 10192 (\*\*)

The average scores and the standard deviation obtained from the test are reported in the following table

Sensory evaluation of Water samples Olfactory testing Measurement unit: Arbitrary units		
<b>Sample</b>	<b>Average score</b>	<b>Standard deviation</b>
<b>PTFE G405 Plate</b>	1.3	0.4

## 6) VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 177.1550.(\*)

### 6.1) Total extractives

The values obtained with foodstuffs simulants, according to **FDA 177.1550** and expressed in **mg/in<sup>2</sup>**, are reported in the following table.

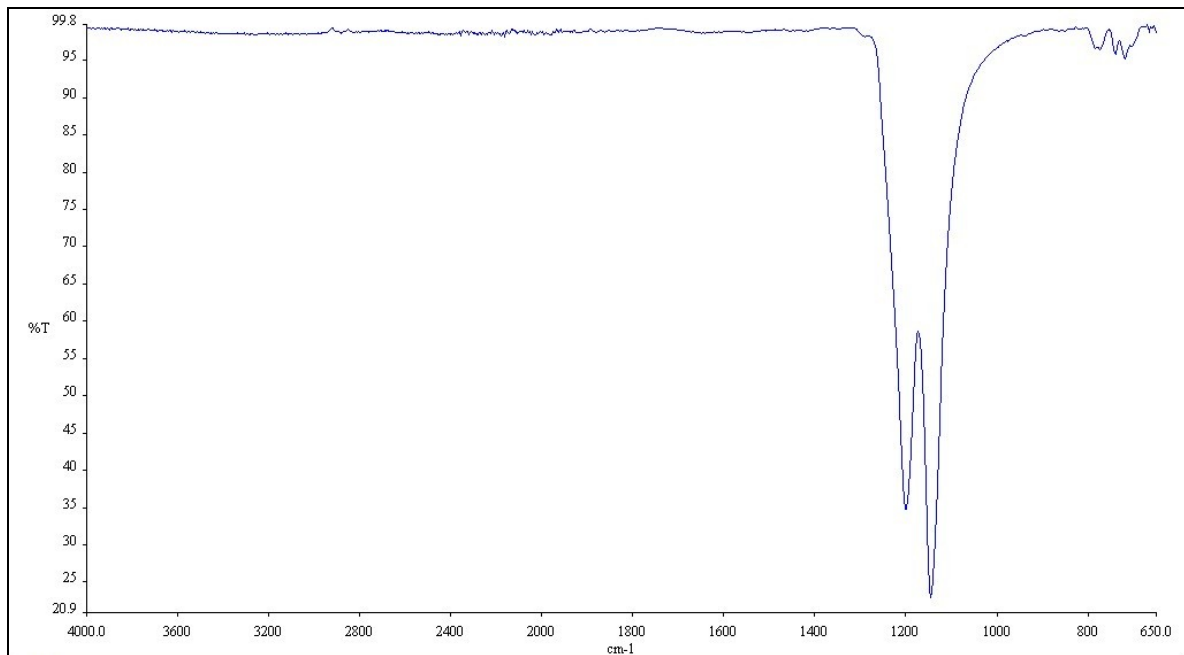
PTFE G405 Plate			
Contact simulant	Test conditions	Measured Value	Limit Value
Distilled water	2 hours at reflux	< 0.01	0.2
Ethanol 50 % v/v	2 hours at reflux	< 0.01	0.2
n-heptane	2 hours at reflux	< 0.01	0.2
Ethyl-acetate	2 hours at reflux	< 0.01	0.2

### 6.2) FLUORIDE EXTRACTIVES

PTFE G405 Plate		
contact simulant	fluoride mg/in <sup>2</sup>	Limit value
Distilled water	< 0.01	0.03
Ethanol 50 % v/v	< 0.01	0.03
n-heptane	< 0.01	0.03
Ethyl-acetate	< 0.01	0.03

### 6.3) IDENTIFICATION OF COATING BY FTIR SPECTROSCOPY

The spectrum below demonstrates that the coating is PTFE.



### 7) VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 175.300

The values obtained with foodstuffs simulants, according to **FDA 175.300** and expressed in **mg/in<sup>2</sup>**, are reported in the following table.

PTFE G405 Plate			
Contact simulant	Test conditions	Measured Value	Limit Value
Distilled water	2 hours at 250 F	< 0.01	0.5
Ethanol 8 % v/v	2 hours at 150 F	< 0.01	0.5
n-heptane	2 hours at 150 F	< 0.01	0.5



**RAPPORTO DI PROVA**  
*(Test Report)*

Pag. 12  
di/of  
pag. 12

N° 0240\FPM\FDC\11\_10

Data: 12/04/2011  
Date:

**CONCLUSIONS**

In the chosen test condition the sample **PTFE G405 Plate** is suitable to be used in contact with aqueous, alcoholic and oily or fatty foodstuffs for which simulants A, C and D are used and as stated in the EU Reg.n.10/2011.

The sample is not suitable to come into contact with acidic foodstuffs for which simulant B is used.

The sample is also suitable to be used in contact with foodstuffs in accordance with US legislation (FDA 21 cfr. § 177.1550).

The sample tested by this Laboratory are therefore suitable to come in contact with foodstuff mentioned above on condition that they have been produced employing the monomers, additives and technical support agents according to in force legislation, specific migrations are respected and they do not induce any organoleptic modification on foodstuff.

Date  
12/04/2011

Division Head  
Alberto Taffurelli

Managing Director  
Pasqualino Cau