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 **AIMPLAS**

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REGISTRO DE SALIDA

COMPANY

INICIATIVAS Y PROYECTOS HOSTELEROS, S.L.
POLÍGONO INDUSTRIAL EL GUIJAR
C/ PINO, 19 NAVE-4
28500-ARGANDA DEL REY (MADRID)
ESPAÑA (SPAIN)

Valencia Parc Tecnològic
Calle Gustave Eiffel, 4
Apartado de correos 51
46980 PATERNA Valencia - España

Tel.: +34 96 136 60 40
Fax: +34 96 136 60 41
<http://www.aimplas.es>
email: info@aimplas.es



TEST/S

A.- Tests performed to verify the fulfilment of Spanish legislation RD 866/2008, European Directive 2002/72/CE and their amendments (2004/1/CE, 2004/19/CE, 2005/79/CE, 2007/19/CE): plastic articles intended to come into contact with foodstuffs.

A1.- Overall migration into aqueous simulant according to standard EN 1186-3 "Materials and articles in contact with foodstuffs-Plastics-Part 3". Test methods for overall migration into aqueous food simulant by total immersion" (November 2002).

A2.- Overall migration into aqueous simulant by total immersion according to standard EN 1186-9 "Materials and articles in contact with foodstuffs-Plastics-Part 9". Test methods for overall migration into aqueous food simulant by article filling" (November 2002).

A3.- Specific migration limit of 2, 2-Bis(hydroxyphenyl)propane (Bisphenol A) in alcoholic simulant. (*)

A4.- Residual content of carbonyl chloride (phosgene) in plastic materials. (*)

B.- Tests performed to verify the fulfilment of USA legislation, Food and Drugs Administration (FDA) CFR 21, 177.1580.

B1.- Identification of material by FTIR according to CFR 21, 177.1580.

B2.- Determination of nonvolatile extractives in different solvents. (*)

REGISTERED NAME AND / OR DESCRIPTION OF PRODUCT OR SAMPLE/S.

Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.)

- Description: Dispenser (container+tap connection+tap+join+internal cooling tube+lid+base).

- Code: 08/0902/1



TEST PROCEDURE/S

A.- Tests performed to verify the fulfilment of Spanish legislation RD 866/2008, European Directive 2002/72/CE and their amendments (2004/1/CE, 2004/19/CE, 2005/79/CE, 2007/19/CE): plastic articles intended to come into contact with foodstuffs.

A1.- Overall migration into alcoholic simulant by total immersion.

Overall migration into aqueous simulant according to standard EN 1186-3 "Materials and articles in contact with foodstuffs-Plastics-Part 3". Test methods for overall migration into aqueous food simulant by total immersion" (November 2002).

The standard EN 1186-1 "Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration", determines the migration test conditions to apply to each type of sample and of application. For our test sample, the test conditions are:

<i>Simulant</i>	<i>Exposure time</i>	<i>Exposure temperature</i>	<i>Type of contact simulant/sample</i>
Simulant C (Ethanol 50%)	10 days	40°C	Immersion

A2.- Overall migration into alcoholic simulant by article filling.

The determination of the overall migration is done according to standard EN 1186-9 "Materials and articles in contact with foodstuffs-Plastics-Part 9: Test methods for overall migration into aqueous food simulant by article filling" (November 2002).

The standard EN 1186-1 "Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration", determines the migration test conditions to apply to each type of sample and of application. For our test sample, the test conditions are:

<i>Simulant</i>	<i>Exposure time</i>	<i>Exposure temperature</i>	<i>Type of contact simulant/sample</i>
Simulant C (Ethanol 50%)	10 days	40°C	Article filling

Simulant exposure was done filling the article to the lowest volume indication.



A3.- Specific migration limit of 2, 2-Bis(hydroxyphenyl)propane (Bisphenol A) in alcoholic simulant.

The determination of the specific migration is done according to standard UNE-EN 13130-1:2000. Materials and articles in contact with foodstuffs. Plastics substances subject to limitation. Part 1: Guide to the test methods for the specific migration of substances from plastics into foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.

For our test sample, the test conditions are:

<i>Simulant</i>	<i>Exposure time</i>	<i>Exposure temperature</i>	<i>Type of contact simulant/sample</i>
Simulant C (Ethanol 50%)	10 days	40°C	Immersion

After the exposure time, the simulant is analyzed by means high performance liquid chromatography with a mass spectrometry detector (LC/MS). The test is based on the standard UNE-CEN/TS 13130-13 "Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants.

A4.- Residual content of carbonyl chloride (phosgene) in plastic materials. (*)

The determination of phosgene is carried out dissolving the polymer followed by a derivatization with 2-aminophenol. Quantification is done by means high performance liquid chromatography with an UV detector.

B.- Tests performed to verify the fulfilment of USA legislation, Food and Drugs Administration (FDA) CFR 21, 177.1580.

B1.- Identification of material by FTIR according to CFR 21, 177.1580

- The analysis is done according internal procedure QE-15
- Instrument: Fourier Transformed Infrared Spectrophotometer NICOLET 510
- Measurement method: Transmission
- Scans: 10
- Resolution (cm⁻¹): 4
- Scanning range (cm⁻¹): 4000-400
- Sample preparation: Film from the sample.

B2.- Extractives limitations according to CFR 21,177.1580.

Sample extraction is done with the boiling solvents during 6 hours. Soluble fraction percentage is determined for each solvent by evaporation and weighing. The solvents to be used are: distilled water, ethanol 50% and n-heptane. The test is performed twice per sample.



RESULT/S

A.- Tests performed to verify the fulfilment of Spanish legislation RD 866/2008, European Directive 2002/72/CE and their amendments (2004/1/CE, 2004/19/CE, 2005/79/CE, 2007/19/CE): plastic articles intended to come into contact with foodstuffs.

A1.- Overall migration into alcoholic simulant by total immersion.

Table 1

Sample	Simulant	Test specimen 1 (mg/dm ²)	Test specimen 2 (mg/dm ²)	Test specimen 3 (mg/dm ²)	Test specimen 4 (mg/dm ²)	Mean values (mg/dm ²)	Uncertainty (k=2)
Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.) (08/0902/1)	C (Ethanol 50%)	<0.8	<0.8	<0.8	<0.8	<0.8	±0.4

Results expressed as mg of migrant per dm² of sample.

- According to Spanish legislation RD 866/2008, European Directive 2002/72/CE and their amendments the maximum overall migration limit for plastic materials and articles in contact with foodstuffs is **10 mg/dm²**. An analytical tolerance of 2 mg/dm² of simulant is admitted for the migration tests with aqueous and alternative oil simulants (iso-octane and ethanol 95%).

A2.- Overall migration into alcoholic simulant by article filling.

Table 2

Sample	Simulant	Test specimen 1 (mg/kg)	Test specimen 2 (mg/kg)	Test specimen 3 (mg/kg)	Test specimen 4 (mg/kg)	Mean values (mg/kg)	Uncertainty (k=2)
Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.) (08/0902/1)	C (Ethanol 50%)	<4	<4	<4	<4	<4	±4

Results expressed as mg of migrant per dm² of sample.

- According to Spanish legislation RD 866/2008, European Directive 2002/72/CE and their amendments the maximum overall migration limit for plastic materials and articles in contact with foodstuffs is **60 mg/kg**. An analytical tolerance of 10 mg/dm² of simulant is admitted for the migration tests with aqueous and alternative oil simulants (iso-octane and ethanol 95%).



A3.- Specific migration limit of 2, 2-Bis(hydroxyphenyl)propane (Bisphenol A) in alcoholic simulant.

Table 3

Sample	Test specimen 1 mg/Kg	Test specimen 2 mg/Kg	Test specimen 3 mg/Kg	Test specimen 4 mg/Kg
Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.) (08/0902/1)	ND	ND	ND	ND

ND = Non detectable. The detection limit is 0.06 mg per kg of simulant.

- According to Annex II of Directive 2002/72/EC the maximum overall migration limit for 2,2-Bis(4-Hydroxyphenyl) propane (Bisphenol A) is 3 mg/Kg of simulant.

A4.- Residual content of carbonyl chloride (phosgene) in plastic materials.

Table 4

Sample	Test specimen 1 (mg/Kg)	Test specimen 2 (mg/Kg)
Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.) (08/0902/1)	<1	<1

- According to Annex II of Directive 2002/72/EC the maximum permitted quantity of carbonyl chloride in the material or article is 1 mg/Kg of product.



B.- Tests performed to verify the fulfilment of USA legislation, Food and Drugs Administration (FDA) CFR 21, 177.1580.

B1.- Identification of material by FTIR according to CFR 21, 177.1580

Sample: Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.)

In the infrared spectra of the analyzed sample characteristic bands of polycarbonate (PC) are observed.

Note: The infrared spectra of the analyzed samples are included in the Annex.

B2.- Extractives limitations according to CFR 21,177.1580.

Table 5

Sample	Solvent	Test specimen 1 (%)	Test specimen 2 (%)	Mean values (%)
Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.) (08/0902/1)	Distilled water	0.051	0.068	0.06 0.01
	Ethanol (50%)	0.057	0.049	0.05 0.01
	Heptane	0.058	0.068	0.06 0.01

- According to FDA CFR 177.1580 total extractives should not exceed 0.15 percent in weight for each solvent.

Eva Bejarano Wieseler
Head of Chemical Laboratory

ANNEX

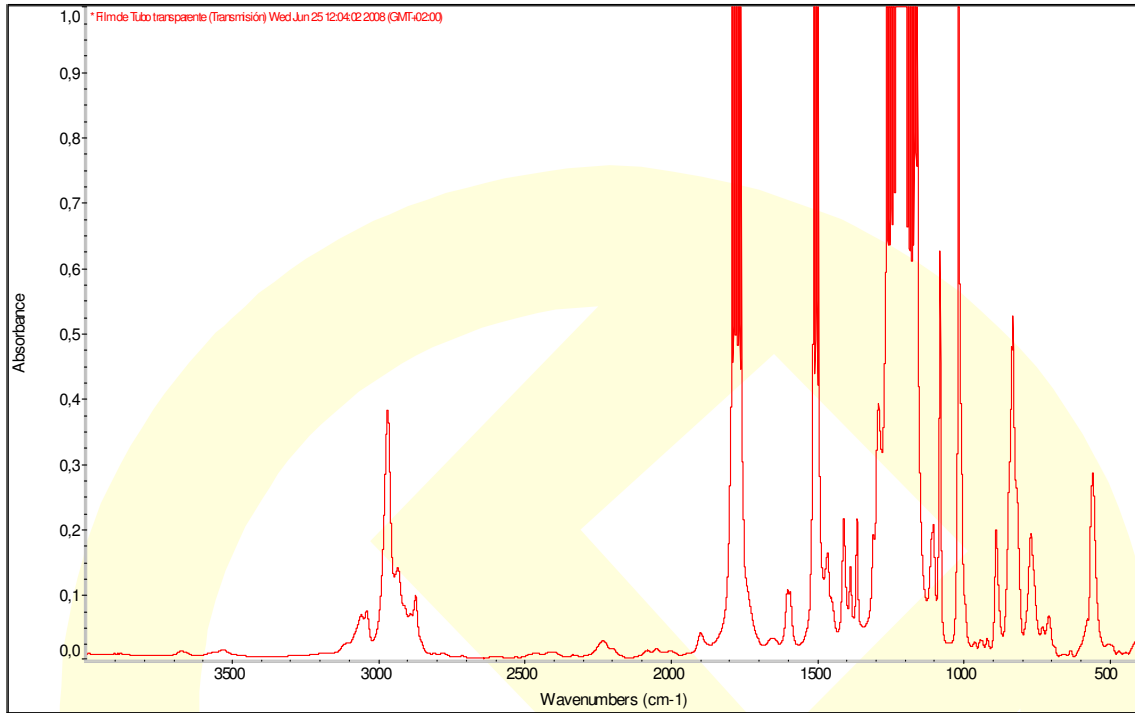


Fig. 1: Infrared spectra of Portable beverage dispenser Metrodispenser (Iniciativas y Proyectos Hosteleros, S.L.).



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