

CUSTOMER
INDUSTRIE PLASTICHE LOMBARDE SPA
Via Leonardo Da Vinci, 13C
21023 BESOZZO VA

Modena (Italy), li 27/07/2010

Analysis beginning date
20/05/2010

TEST REPORT nr. 10E08650-In-0

SAMPLE 10E08650

Description provided by Customer: PHARMASTEEL J4 01 015,1 000,4 - 1 SACCHETTO - DATA ARRIVO CAMPIONE
20/05/2010, CAMPIONAMENTO ESEGUITO DA: COMMITTENTE, TRASPORTO EFFETTUATO DA: CORRIERE.
Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYTICAL TECHNIQUE	ANALYSES ENDING DATE
Migration tests in aqueous simulant Test conditions	The migration test was carried out by total immersion the sample in to the simulant under these conditions: contact time: t= 10 days contact temperature: T= 40°C						DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
Overall migration in distilled water (Simulant A)	< LQ			mg/dm ²	1,0		DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
- LAW LIMIT 10									
Migration tests in acid simulant Test conditions	The migration test was carried out by total immersion the sample in to the simulant under these conditions: contact time: t= 10 days contact temperature: T= 40°C						DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
Overall migration in Acetic Acid 3% (SIM B)	< LQ			mg/dm ²	1,0		DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
- LAW LIMIT 10									

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ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYTICAL TECHNIQUE	ANALYSES ENDING DATE
Migration tests in alcoholics simulant (Sim C) at 50% Test conditions	The migration test was carried out by total immersion the sample in to the simulant under these conditions: contact time: t= 10 days contact temperature: T= 40°C						DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
Overall migration test in ethanol alcohol 50% (SIM C)	< LQ			mg/dm2	1,0		DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010
- LAW LIMIT 10									
Migration tests in fatty simulant Test conditions	The migration test was carried out by total immersion the sample in to the simulant under these conditions: contact time: t= 10 days contact temperature: T= 40°C						DM 21/03/1973GUn°104 20/04/1973;DMn°220 26/04/1993GUn°162 13/07/1993;DMn°735 28/10/1994GUn°1 02/01/1995;DMn°338 22/07/1998GUn°228 30/09/1998;DM n°123 28/03/2003 GU n°125 31/05/2003;DMn°299 22/12/2005GUn°37 14/02/2006;DMn°174 24/09/2008GUn°261 07/11/2008		27/07/2010

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ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYTICAL TECHNIQUE	ANALYSES ENDING DATE
Overall migration in olive oil (Simulant D)	< LQ			mg/dm2	3,0		DM 21/03/1973GUn*104 20/04/1973;DMn*220 26/04/1993GUn*162 13/07/1993;DMn*735 28/10/1994GUn*1 02/01/1995;DMn*338 22/07/1998GUn*228 30/09/1998;DM n*123 28/03/2003 GU n*125 31/05/2003;DMn*299 22/12/2005GUn*37 14/02/2006;DMn*174 24/09/2008GUn*261 07/11/2008		27/07/2010
- LAW LIMIT 10									

END TEST REPORT

THE ORIGINAL DOCUMENT IS IN PDF FILE WITH EMBEDDED DIGITAL SIGNATURE

Opinions and Interpretations - Not included in ACCREDIA accreditation.

EVALUATION OF RESULTS

Considering the subdivision of food products as reported in Encl. II of the Ministry Decree of 26 april 1993 n. 220, under the applied test conditions (contact time and temperature) the analysed sample complies with the overall migration limits set for the following foodstuff classes

All food products for which no migration tests are required and migration tests with the following simulants are required:

- A (moist food products with pH > 4.5)
- B (acid food products with pH<4.5)
- C (food products containing alcohol) and food products for which migration tests are provided for Simulant ethanol 50% :milk (whole milk, partially dehydrated milk, skimmed or semi-skimmed milk) fermented milk such as yoghurt, buttermilk and similar products, Cream and sour cream.
- D (food products based on fatty substances) independent of the application of foreseen reduction coefficients.

For the packaging to be suitable for food contact it is also mandatory that the starting materials are included in the positive lists of regulation enforce and, in case special restrictions are provided for, the compliance with specific limits has to be checked.

Legislative references: D.M. (Ministry Decree) 21-03-73 and following updating - D.M. (Ministry Decree) 220 of 26-04-93 and following updating - Directive 2002/72/CE and following updating.

Test temperature uncertainty = $\pm 1^{\circ}\text{C}$

Notes:

< LQ: = lower than Quantification Limit. Please note that results expressed as '<LQ' may not indicate the absence of the searched parameters in the sample.
U: the reported uncertainty is the expanded uncertainty calculated using a coverage factor equal to 2 which gives a reliability of approximately 95%. For microbiological detections it is reported either the lower and the upper bounds of the confidence interval with a probability of 95% K=2 or the confidence interval itself.
Results coming from microbiological tests are calculated according to the Standard ISO 7218:2007. If the results are reported as <4 (CFU/ml) or <40 (CFU/g), this means that the microorganisms are present in the sample but in amounts less than 4 CFU/ml or 40 CFU/g respectively.
LQ: Quantification Limit. It is the lowest analyte concentration which can be detected at an acceptable precision (repeatability) and accuracy, under well defined conditions.
LD: Detection Limit. It is the lowest analyte concentration which can be detected but not necessarily quantified, under well defined conditions.
Conformity evaluation: values not complying with laws, decrees, national and EU regulations or specifications supplied by the customer are evaluated case by case, also taking into consideration the uncertainty of measure for each single test and the regulations on rounding-off of values, and pointed out when considered as "non conform".
Rec %: Recovery % "+" means that the recovery has been applied to the result. The codes of accredited internal methods must be considered as being preceded by NEOT-DIR/002/. The numeric results between brackets (..) after the expression <LQ are purely indicative of traces that cannot be exactly quantified.

TEST REPORT VALID FOR ALL LEGAL PURPOSES (Italian R.D. 1-3-1928 n°842 (article 16), - Italian Law 19-7-1957 n°679 articles 16 and 18, Italian Ministerial Decree 25-3-1986).

Test Report issued according to the 17025:2005 Standard

DATA and SAMPLE STORAGE: Raw data, chromatographic paths and instrumental reports are stored for 5 years. One control sample is stored for 2 months.

Data expressed in this test report refer only to the sample tested in the laboratory. The description or any other reference concerning the sample are declared by the customer. This Test Report cannot be reproduced except in full. Partial reproductions must be authorized in writing by our laboratory.

LABORATORY MANAGER: DR. GIAN CARLO GATTI - MEMBER OF AOAC N. VM 90231001 - EURCHEM

Approved by Analysis Manager - laboratory PCK

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Laboratory Certified for GLP (Good Laboratory Practice) issued by the Ministry of Health Law Decree 02-03-2007 n.50
QUALIFICATO D.M. 26-2-87 ART. 4 - LEGGE 48/82 PER LA RICERCA APPLICATA E INNOVAZIONE TECNOLOGICA.
Regione Emilia Romagna - AUTORIZZAZIONE Autocontrollo N° 008/MO/008
BNM-Monitoring Fruit and Vegetables approved laboratory - I-Monitoring EDEKA AG Fruit and Vegetables registered laboratory
UNI EN ISO 9001 Certified Laboratory - CERTIQUALITY n° 1522 - CSQA N° 079