

CUSTOMER  
**PLEXISTAB BULGARIA EAD**  
**53 Tsarigradsko Shose**  
**4006 PLOVDIV BULGARIA**

Modena (Italy), li 11/01/2016

Analysis beginning date  
30/11/2015

**TEST REPORT nr. 15S20151-In-0**

**SAMPLE 15S20151**

Description provided by Customer: SAMPLE 1 - BULSTEEL 501N 38MM FOOD QUALITY 50220111 - SAMPLE ARRIVED ON 27/11/2015 - THE SAMPLE HAS BEEN TAKEN BY THE CUSTOMER. THE TRANSPORT HAS BEEN MADE BY CARRIER.  
Sample Condition on Receipt: Room temperature

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
<b>MIGRATION TESTS IN ACETIC ACID 3% SIMULANT</b>								
- Test conditions	40°C - 10 days						*	31/12/2015
- Contact conditions	Filling						*	31/12/2015
- Surface/volume ratio test	0,9			cm2/cm3			*	31/12/2015
Overall migration test 1 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 2 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 3 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Average value of overall migration in 3% acetic acid [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
<i>- Limite (D.M. 21/03/1973 e smi - Reg. CE 10/2011 e smi): 10</i>								
<b>MIGRATION TESTS IN 20% ETHANOL</b>								
- Test conditions	40°C - 10 days						*	31/12/2015
- Contact conditions	Filling						*	31/12/2015
- Surface/volume ratio test	0,9			cm2/cm3			*	31/12/2015
Overall migration test 1 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 2 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 3 [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
Average value of overall migration in 20% ethanol [MP]	< LQ			mg/dm2	1,0		[MP]	31/12/2015
<i>- Limite (D.M. 21/03/1973 e smi - Reg. CE 10/2011 e smi): 10</i>								
<b>MIGRATION TESTS IN 50% ETHANOL</b>								
- Test conditions	40°C - 10 days						*	31/12/2015
- Contact conditions	Filling						*	31/12/2015
- Surface/volume ratio test	0,9			cm2/cm3			*	31/12/2015
Overall migration test 1 [MP]	3,7			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 2 [MP]	4,2			mg/dm2	1,0		[MP]	31/12/2015
Overall migration test 3 [MP]	4,7			mg/dm2	1,0		[MP]	31/12/2015

Continued...

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GMP Pharmaceutical Laboratories Authorized by AIFA Italian Medicine Agency n° aM- 55/2015.  
Laboratorio Qualificato D.M. 26-2-87 Art. 4 - Legge 46/82 per la Ricerca Applicata e Innovazione Tecnologica.  
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## TEST REPORT nr. 15S20151-In-0

**SAMPLE 15S20151**

ANALYSIS DESCRIPTION	RESULT	U	REC. %	UNIT OF MEASURE	LQ	LD	METHOD	ANALYSES ENDING DATE
Average value of overall migration in 50% ethanol [MP] - Limite (D.M. 21/03/1973 e smi - Reg. CE 10/2011 e smi): 10	4,2	± 0,8		mg/dm <sup>2</sup>	1,0		[MP]	31/12/2015

### END TEST REPORT

The original document is a PDF file with Digital Signature: 15S20151-In-0-DigitalSignature.pdf

#### Notes and method reference:

< 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/Amd 1:2013. 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 numeric results between brackets (..) after the expression <LQ are purely indicative of traces that cannot be exactly quantified.

Methods marked with an asterisk (\*) are not accredited by ACCREDIA (UNI CEI EN ISO/IEC 17025)

#### NOTES OF PARAMETERS:

[MP]: Metodo:DM21/03/1973 GUn°104 20/04/1973; DMn°220 26/04/1993 GUn°162 13/07/1993;DMn°735 28/10/1994 Gn°1 02/01/1995;DMn°338 22/07/1998 GUn° 228 30/09/1998; DM n° 123 28/03/2003 GU n° 125 31/05/2003; DM n° 299 22/12/2005 GU n° 37 14/02/2006;DMn°174 24/09/2008 GUn°261 07/11/2008;RegUEn°10/2011GUUE L12 15/01/2011;UNI EN 1186:2003 (ad esclusione delle parti 10, 11, 15).

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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#### EVALUATION OF RESULTS

Under the applied test conditions (contact time and temperature) the analysed sample complies with the overall migration limits set for the following foodstuff classes:

- Acid food products with pH<4.5 for which it is provided the use of the simulant B = 3% Acetic Acid
- Food products containing alcohol up to 20% and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic for which it is provided the use of the simulant C = 20% ethanol
- Food products containing alcohol up to 50% and food products for which it is provided the use of the simulant D1 = 50% ethanol

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 - Regulation UE n.10/2011 and following updating -

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