

Certificate Quality Department

B571 - DECLARATION OF COMPLIANCE TO REGULATIONS ON MATERIALS INTENDED TO COME INTO CONTACT WITH FOOD as per Article 16 of REGULATION (EC) N° 1935/2004

Trelleborg Izarra, S.A.U. hereby certifies our compliance with materials and articles intended to come into contact with food, as per article 16 of REGULATION (EC) N° 1935/2004.

We hereby declare that the materials intended to come into contact with food entering into the composition of our products under reference **B571** belong to the category of materials RUBBER (as per Annex I of regulation EC 1935/2004)

We declare that our products comply with the requirements of:

- REGULATION (EC) N° 1935/2004, dated 27/10/2004
- REGULATION (EC) N° 2023/2006., dated 22/12/2006

This declaration is based on test references E16-20347-2, carried out on 19/12/2016, in an external Laboratory according to specifications of "l'article 7 de l'arrêté du 9 novembre 1994" of France:

Overall migration test result (OML) - EU 10/2011 (EN1186)

Simulants	Simulant Media	Time Temperature	Migration of substances	Limit	Units
D1	50% Ethanol	3x2 hours, 40°C	Overall migration	≤ 10	mg/dm ²
D2	Vegetable oil	2 hours, 40°C	Overall migration	≤ 10	mg/dm ²
B	3% Acetic Acid	3x2 hours, 40°C	Formaldehyde	≤ 3	mg/kg
			Primary Aromatic Amines	≤ 1	mg/kg
			n-nitrosamines	≤ 1	µg/dm ²
			n-nitrosables substances	≤ 10	µg/dm ²

FVOS and Peroxydes

Material content	Time Temperature	Migration of substances	Limit	Units
Free volatil organic substance	4 hours, 105°C	Average FVOS	≤ 0,5	%
Residual peroxides	/	Peroxides	≤ 0,08	%

Additionally, **B571** is in compliance with FDA 21 CFR Part 177.2600 according to migration analysis, using as simulants Distilled Water for Aqueous Food and n-Hexane for Fatty Food. Test Reference is P12-13967 carried out on 13/07/12, in an external Laboratory.

Extraction test condition CFR 21&177.2600:

Test	Limit (mg/in²)
Extraction in distilled water 7 hours	≤ 20
Extraction in distilled water 2 hours supplementary	≤ 1
Extraction in n-Hexane 7 hours	≤ 175
Extraction in n-Hexane 2 hours supplementary	≤ 4

For information, we confirm furthermore that these materials contain no phthalate and no bisphenol A.

B571 is free of Animal Derived Ingredients (ADI).



María Gutiérrez-Cortines
Izarra, 11/12/2020
Quality Department



TEST REPORT

SUBJECT N°/REPORT: P-12-13967/I

CUSTOMER: **TRELLEBORG IZARRA, S.A.U**

ADDRESS: San Vicente, 23
01440 IZARRA (ALAVA)

TEST MATERIAL:	B57100 NBR BLANCA ALIMENTARIA
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DATE OF RECEPTION: 13.07.12

DATE OF ANALYSIS: 13.07.12 to 12.09.12

N° OF SHEETS

7

(INCLUDING THIS SHEET)

The results of analysis are referred to the test materials.

This report cannot be copied without GAIKER® authorisation, with the exception of the complete report.

This test report is a translation of the original P-12-13967 in Spanish. In case some conflict arises, will prevail Spanish version.


 Iratxe Zuazola
 Laboratory Co-ordinator



Zamudio, 12th September 2012

MATERIAL

One sample of elastomeric material has been received from **TRELLEBORG IZARRA, S.A.U.** The test specimen has been coded as follows:

Your code

B57100

NBR BLANCA ALIMENTARIA

GAIKER's Code

P-12-13967-A-1

TEST

It was requested to perform a migration test according to FDA 21 CFR Part. 177. Indirect Food Additives: Polymers. Sec 177.2600 Rubber articles intended for repeated use.

TEST DESCRIPTION

Samples in contact with aqueous food

The food contact surface has been extracted with distilled water at reflux temperature in two steps:

- First extraction: during 7 hours.
- Second extraction: during 2 hours

Samples in contact with fatty food

The food contact surface has been extracted with n-hexane at reflux temperature in two steps:

- First extraction: during 7 hours.
- Second extraction: during 2 hours

P.A. 

RESULTS

Migration results are the following ones:

SAMPLE	TEST	STANDARD	RESULT mg/dm ²	RESULT mg/in ²	LIMIT mg/in ²
B57100 NBR BLANCA ALIMENTARIA P-12-13967-A-1	Distillate water 7 Hours Reflux T ^a	FDA 21FCR 177.2600	32,3	2,1	20
B57100 NBR BLANCA ALIMENTARIA P-12-13967-A-1	Distillate water 2 Hours Reflux T ^a	FDA 21FCR 177.2600	10,5	0,7	1

SAMPLE	TEST	STANDARD	RESULT mg/dm ²	RESULT mg/in ²	LIMIT mg/in ²
B57100 NBR BLANCA ALIMENTARIA P-12-13967-A-1	n-Hexane 7 Hours Reflux T ^a	FDA 21FCR 177.2600	283	18,3	175
B57100 NBR BLANCA ALIMENTARIA P-12-13967-A-1	n-Hexane 2 Hours Reflux T ^a	FDA 21FCR 177.2600	51,1	3,3	4

The tested material is compliant with FDA 21 CFR Part. 177. Indirect Food Additives: Polymers. Sec 177.2600 Rubber articles intended for repeated use for contact with aqueous food and with fatty food.



Inmaculada Angulo
Test Report Responsible
Zamudio, 12th September 2012

ENSAYO DE MIGRACIÓN GLOBAL EN SIMULANTES ACUOSOS

N° ASUNTO :	P-12-13967	FECHA DE ENSAYO :	02/08/2012
MATERIAL :	P-12-13967-A-1	NORMA :	FDA 21 CFR 177.2600
ANALISTA:	L.DOMINGUEZ		

REFERENCIA	P-12-13967-A-1
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SIMULANTE	DISTILLED WATER
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CONDICIONES	REFLUX TEMPERATURE/ 2 HOURS
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	MUESTRA 1	MUESTRA 2	MUESTRA 3	MUESTRA 4
ÁREA (dm ²)	1,00	1,00	1,00	
ESPESOR (mm)	2,00	2,00	2,00	
PESO INICIAL DE LA MUESTRA (gr.)	38,5941	48,2118	38,4811	
PESO FINAL DE LA MUESTRA (gr.)	38,6042	48,2227	38,4915	
MIGRACIÓN GLOBAL (mg / dm ²)	10,1	10,9	10,4	

VALOR MEDIO DE LA MIGRACIÓN GLOBAL (mg / dm²) 10,5

DESVIACIÓN ESTÁNDAR DE LA MIGRACIÓN GLOBAL (mg / dm²) 0,4

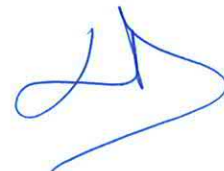
GAIKER estima la incertidumbre del presente ensayo, que está a disposición del cliente si éste la desea conocer

Los valores medios de todas las muestras ensayadas cumplen la tolerancia analítica indicada en el Reglamento (UE) 10/2011 y en las Normas UNE EN 1186-3: 2002, UNE EN 1186-5: 2002 y UNE EN 1186-9: 2002.

OBSERVACIONES:

1.- Número de muestras utilizadas. (indicar las muestras usadas)

2.- Otras observaciones.





Quality Department Certification

Date	26/02/16
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SUBJECT: R490 and B571

PA Elastomer Laminates hereby certifies that our fluoroelastomers ref. R490 and B571 are silicone free.

Nevertheless, in the case of R490, for articles from 5 mm thickness and over, due to production process it may have some trace of silicone on the surface (highly diluted).

In our production for B571 (food grade), we do not use silicone.



Izarra, 26/02/16
on behalf of PA Elastomer Laminates
Quality Department
María Gutiérrez-Cortines