



LABORATORIO PER LA CERTIFICAZIONE E RICERCA  
SUI SISTEMI ELASTOMERICI

con il patrocinio del C.N.R.



To

F.M.I. S.p.A.

Via Taranto, 10/12

Date, 31<sup>st</sup> October, 2012

TR n° **595<sub>bis</sub>/2012**

Ref. Your Ord.n°12/02179 of 24.09.2012 25036 San Pancrazio di Palazzolo (BS)

Received 03.10.2012

Start tests 17.10.2012

End tests 26.10.2012

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**T E S T R E P O R T**

**Subject:** DETERMINATION OF THE EXTRACTIVES IN THE SIMULATORS OF FOODS,  
ACCORDING TO FDA, ON A PTFE SHEET

**PTFE Sheet  
Thickness 2 mm**

**SICHEM S60**

Test Methods  
**FDA-CFR 21  
Parts 170 to 199  
Item 177.1550**

Requirements

Total extractives in the simulators of foods after  
2 hours at the reflux temperature

Substrate	mg/in <sup>2</sup>	mg/in <sup>2</sup>	Requirements
• Distilled water	0,20		max 0,2
• n.heptane	0,18		max 0,2
• 50% ethanol solution in water (v/v)	0,06		max 0,2
• ethylacetate	0,15		max 0,2

Specific fluoride extractives in the simulators of  
foods after 2 hours at the reflux temperature

Substrate	mg/in <sup>2</sup>	mg/in <sup>2</sup>	Requirements
• Distilled water	Not detectable* (<0,003)		max 0,03
• n.heptane	Not detectable* (<0,003)		max 0,03
• 50% ethanol solution in water (v/v)	Not detectable* (<0,003)		max 0,03
• ethylacetate	Not detectable* (<0,003)		max 0,03

\* Detection Limit: 0,003 mg/in<sup>2</sup>

**REMARK:** The values of the all extractives **are in compliance** with the Requirements of the FDA-CFR 21 – Parts 170 to 199 – Item 177.1550.

The sampling has been carried out by the Customer.

The contained results refer only to the tested sample.

This report cannot be partially reproduced without the laboratory approval.

*E. Badomer*  
**E. Badomer, Operator**

*F. Negroni*  
**F. Negroni, Director**

