

DIVISIONE: **FOOD PACKAGING MATERIALS**
DIVISION:

LABORATORIO:
LABORATORY:

FOOD CONTACTS

RAPPORTO DI PROVA
(Test Report)

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N° 0457\FPM\FDC\11_2

Data: 13/05/2011
Date:

IDENTIFICAZIONE E DESCRIZIONE DEL CAMPIONE:
SPECIMEN DESCRIPTION:

JUGITEC PHARMA protective glove, EPDM, black color

DATI IDENTIFICATIVI DEL CLIENTE:
CLIENT:

JUNG GUMMITECHNIK GmbH
Robert-Bosch-Strasse, 12
D – 64683 Einhausen

NORMA DI RIFERIMENTO:
REFERENCE STANDARD:

Federal Regulations, FDA (Food and Drug Administration), Vol. 21, Cap. 177.2600

DISTRIBUZIONE ESTERNA:
OUTSIDE DISTRIBUTION:

POHLING SRL
Sig. Ralf Pohling

DISTRIBUZIONE INTERNA:
INSIDE DISTRIBUTION:

Copy to Division Head

ENTE DI ACCREDITAMENTO:
ACCREDITATION BODY:

GENERALITIES

- Sample receiving date: 28/04/2011
- Analysis start date: 05/05/2011
- Analysis end date: 13/05/2011
- Deviation from test methods: NO

SAMPLE DESCRIPTION

JUGITEC PHARMA protective glove, EPDM, black color

SAMPLING

The initial sampling has been done by the customer.

The sampling for the test has been done drawing casually part of the sample in our possession.

DECLARATION

The test results of the present report are related exclusively to the tested sample.

The present test report cannot be partially reproduced without the authorization of CSI managing Director.

The uncertainties (*) are estimated as extended uncertainty obtained multiplying the standard uncertainty by the coverage factor k corresponding to a confidence level of about 95%. Normally, this factor = 2.

PERFORMED DETERMINATIONS

- 1) **VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 177.2600.**

Testing of food contact second Code of Federal Regulations, FDA, vol. 21, Chapter 177.2600, "Elastomers for repeated use" (Rubber articles intended for repeated use.)

Determination of the maximum extractives fraction in distilled water and n-hexane at reflux temperature after 7 hours and additional 2 hours(see paragraph 177.2600 ns. Edition).

The test was carried out by immersion of the samples tested in liquid simulants.

L.O.D. 0.10 mg/in²



CSI
Certificazione e Testing

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RESULTS

- 1) **VERIFICATION OF THE SUITABILITY TO CONTACT WITH FOODSTUFF ACCORDING TO FEDERAL REGULATIONS, FDA (FOOD AND DRUG ADMINISTRATION), VOL. 21, CAP. 177.2600.**

JUGITEC PHARMA protective glove, EPDM, black color			
Contact simulant	Test conditions	Measured Value	Limit Value
Distilled water	7 hours	0.54 mg/in ²	20 mg/in²
	+ 2 hours	0.23 mg/in ²	1 mg/in²

JUGITEC PHARMA protective glove, EPDM, black color			
Contact simulant	Test conditions	Measured Value	Limit Value
n-hexane	7 hours	84.53 mg/in ²	175 mg/in²
	+ 2 hours	0.36 mg/in ²	4 mg/in²

CONCLUSIONS

According to the documentation supplied and the parameters under control, you have requested, the sample **JUGITEC PHARMA protective glove, EPDM, black color** complies with FDA Vol.21 CFR 177.2600.

The compliance doesn't refer to the compositional requirements of the tested sample which are, or remain, under the customer responsibility.

Date
13/05/2011

Division Head
Alberto Taffurelli

Managing Director
Pasqualino Cau