Test report No: **412.754/1e** Date: **2014-08-27**

Sponge Rubber
Test according to FDA 21CFR 177.2600

Englisch Version

Client:

Test item:	Sponge rubber
Specification:	Test according to FDA 21CFR 177.2600 (Issue 01.April.2013)
Order:	written on 2014-02-20
Date of sampling:	no sampling by OFI employees
Location of sampling:	no sampling by OFI employees
Receipt of samples:	2014-02-24
Re:	Nov/Ha

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1 SCOPE OF WORK

As per order a sponge rubber should be tested on conformity with the requirements of FDA 21 CFR Section 177.2600 for rubber articles intended for repeated use in contact with aqueous and fatty food.

2 SCOPE OF APPLICATION

The results given in this test report have been obtained under the specific conditions of the individual tests. They shall serve as proof for the client of the conformity of the samples tested with the requirements of the regulation given.

The test report has originally been drawn up in German. The German version shall be the authentic one and prevail over the English one for all matters of interpretation and construction. The English version shall only be deemed a translation for information purposes.

3 SAMPLE MATERIAL

For testing purpose 2 sheets (10x10x1.8 cm) made of sponge rubber were provided by the client. The formulation of the material meets the requirements of FDA 21 CFR Section 177.2600 (Issue 01. April 2013).

4 DURCHFÜHRUNG DER PRÜFUNGEN

Testing was done from 2011-04-14 to 2011-04-20.
The tests were carried out in the individual technical departments within the scope of competence of the authorised signatories according to the OFI QM manual.

The tests were performed according to the instructions specified in Section 177.2600 e) of FDA CFR <21>. The estimation of total extractives was performed by extracting the material with highly purified water (aqueous food) and hexane (fatty food). The extractions were performed at reflux temperature for 7 hours followed by a second extraction period of 2 hours. A ratio of surface/volume of 7 $inch^2$ / 100 ml was applied. The extracts were evaporated to dryness using a rotation evaporator (Rotavapor # 2.774) The residues were determined gravimetrically (Analytical balance # 2.264).

5 RESULTS

The analytical findings of the tests are shown in table 1 together with the requirements specified by of FDA CFR <21> Sec. 177.2600 for rubber articles intended for repeated use in contact with aqueous and fatty food.

Table 1: results of the test for global migration of sponge rubber (extraction using purified water and hexane under reflux conditions)

Parameter	*results*		*requirements FDA*
	1)	*2)*	
Global migration water, 1. extraction period (7 h)	5,7	2,3	< 20 mg / inch^2
Global migration water, 2. extraction period (2 h)	1,5	0,6	< 1 mg / inch^2
Global migration hexane, 1. extraction period (7 h)	49,9	19,9	< 175 mg / inch^2
Global migration hexane 2. extraction period (2 h)	6,9	2,8	< 4 mg / inch^2

1) Results for 1 inch^2 of the sponge rubber surface, without considering the fact that the surface actually in contact with the extraction medium is much higher due to the open cell foam structure.

2) Considering an enlargement of the tested surface by a factor of 2.5 due to the open cell foam structure. For the estimation of this factor all open foam cells of a surface of inch^2 were measured under the light microscope (Olympus Zoom-Stereo-Microscope # 784). Based on these results the "inner surface" of the cells (which also was in contact with the extracting medium) was calculated approximately.

Considering its special surface structure the tested samples of the sponge rubber of the company BOSIG GmbH meet the requirements of FDA 21CFR 177.2600 (Issue 1.April.2013) specified for rubber products intended for repeated use in contact with aqueous and fatty food.

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comprises 4 sheets 1 table(s), 0 picture(s), 0 attachment(s).

Director in charge

Date 27.08.2014

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