

Vienna, 2016-04-28

Test report No. 418.231/3H

Test of rubber plates according to FDA CFR 21 177.2600 and BfR XXI

Client: Semperit Technische Produkte GmbH
 Triester Bundesstraße 26
 AT – 2632 Wimpassing

Test item: plates made of rubber compound "A 618"

Place of manufacture: Semperit Technische Produkte GmbH, AT – 2632 Wimpassing

Order: written order on 2015-12-15 by Mr. Braun

Date of sampling: no samples were taken by OFI staff, samples were sent by client

Receipt of samples: 2015-12-18

Type of Test: Test in accordance with „FDA 21 FOOD AND DRUGS PART 177.2600 Rubber articles intended for repeated use (Revised 2016-04-01)“ and „BfR XXI Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk (Stand vom 2015-07-01)“

The formulation of "A 618" has been disclosed by the material supplier and was checked on conformity with stated regulations.

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.

Testing was performed according to "FDA 21 177.2600 test point (e)" and "BfR XXI Chapter 2.1 Category 1". The specified test conditions are given in table 1, the used methods in table 2 on the reverse side of this test report.

Test period: 2016-03-21 to 2016-04-07

Results: The results of the individual tests can be seen in table 3 on the reverse side of this test report.

Table 1: test conditions

Test parameter	Method	Apparatus/OFI device
FDA 21 177.2600	FDA 21 177.2600 (e)	Laborota 4003 rotary evaporator / #2.774 Entris 224i-15 analytic scale / #3.175
BfR XXI	Chapter 2.1	Laborota 4003 rotary evaporator / #2.774 Entris 224i-15 analytic scale / #3.175 Rumed climate chamber 4301 / #2.780

Table 2: specified test conditions

Test	Surface	Migration temperature	Migration periods	Test water
FDA 21 177.2600 Test point (e)	4 sqj	100°C	9h (7h + 2h)	Ultra pure water MilliQ
BfR XXI Chapter 2.1	0,5dm ²	40°C	240h	Ultra pure water MilliQ



Non-accredited procedures applied have been named as such.

418.231/3H

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Table 3: Results of testing

Parameter (unit)	Residue after first migration period	Residue after second migration period	Requirement ¹
FDA 21 177.2600 test point (e) (mg/sqi)	11,15	0,225	≤ 20 (first migration) ≤ 1 (second migration)
BfR XXI chapter 2.1 (mg/dm ²)	12,8	---	≤ 50

The tested plates made out of "A 618" fulfil the requirements given by "FDA 21 FOOD AND DRUGS PART 177.2600 Rubber articles intended for repeated use (Revised 2016-04-01)" for rubber material in contact with aqueous food and the requirements given by "BfR XXI Chapter 2.1 BfR XXI Bedarfsgegenstände auf Basis von Natur- und Synthetikgummi (Stand vom 2015-07-01)" for Category 1.

This test report is valid for 5 years from the date of issue providing that there has been no change in their formulation, in the relevant substance assessments (restrictions in the positive lists) or in the manufacturing process.

The results given in this test report have been obtained under the specific conditions of the individual tests. As a rule they are not the only criteria for assessing the product in question and its suitability for a specific purpose of application. The test results only relate to the samples tested. Test Reports may be made available to third parties, either free of charge or against payment, if the full wording of the Test Report is given and if OFI is expressly named as the author. All tests applied are subject to a quality assurance programme according to EN ISO/IEC 17025:2005. The General Terms and Conditions of OFI Technologie & Innovation GmbH shall apply as amended; they are available for download on the Internet (<http://www.ofi.at>).

 <p>This test report comprises 2 sheets 3 tables and 0 appendixes</p>	Date:	28.04.2016
	For the testing staff	Nadine Haas
	Date:	28.04.2016
	Director in charge:	Christoph Wirrer, BSc.

¹ Requirements given by the FDA 21 177.2600 (e) and BfR XXI chapter 2.1