OFI Technologie & Innovation GmbH
Firmensitz: 1030 Wien, Franz-Grill-Straße 5, Objekt 213
t: +43 1 798 16 01 - 0 | office@ofi.at | www.ofi.at

Test report

Report No.: 2101803 **Project / Capture No:** 15376 / 1He-k1 **Date:** 2022-03-31

This is the English version of test report 2101803 / 15376 / 1H-k1

This report replaces the report 2101803/15376 / 1He

Client / Producer:	Semperit Technische Produkte GmbH Triester Bundesstraße 26 AT – 2632 Wimpassing
Subject:	Testing plates with Elastomerquality P 627 (Formulation disclosed on2021-08-18)
Task:	Test according to FDA CFR 21 177.2600 „*FDA 21 FOOD AND DRUGS PART 177.2600 Rubber articles intended for repeated use (Revised 2022-01-06)*“
Order:	2021-09-09
Receipt of samples:	2021-09-14
Period of testing:	2021-09-14 bis 2022-02-10

1 SCOPE OF WORK

As ordered the received samples – with consideration of existing test a/o inspection results from accredited laboratories – were tested for fulfilment of the requirements given by FDA 21 177.2600 with regards to the formulation and the paragraphs (e) and (f).

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 to the requirements of the product standard(s) given.

In Table 4, the note "provisional" has been deleted and the sample formulation check has been added to the footnote 1.

3 SAMPLE MATERIAL

The client provided following samples described in Table 1.

Table 1: Sample material description

Sample No.	Sample description
1	Testing plates made out of P 627

4 TESTS

The tests were carried out in the individual technical departments within the scope of competence of the authorized signatories according to the OFI QM manual.

The formulation of the material used was also checked for conformity with stated Guideline. The specified test conditions, the used methods and the used devices are given in the following tables.

Submitted external test / inspection results:

- None

Table 2: Used methods and devices

Test parameter	Method	Apparatus / OFI device
FDA 21 177.2600	FDA 21 paragraphs (e) and (f)	Loborota 4003 Rotary Evaporator / #2.774 Entris 224i-15 Analytical scale / #2.894

Table 3: Used methods

Test	Surface	Volume	Migration temperature	Migration periods	Test water
FDA 21 177.2600 Paragraph (e)	0,65 sqi	1000 mL	100°C	9h (7h + 2h)	Ultra purewater MilliQ
FDA 21 177.2600 Paragraph (f)	0,65 sqi	1000 mL	100°C	9h (7h + 2h)	n- Hexane

5 RESULTS

The results of all tests are shown in Table 4 to Table 5.

Table 4: Summary of general results

Parameter	Test
Composition Requirements	tested and fulfilled[1]

Table 5: Results for Elastomerquality P627

Parameter (Unit)	Backlog after first migration	Backlog after second migration	Requirement[2]
FDA 21 177.2600 Paragraph e (mg/sqi)	2,8	0,33	≤ 20 (first migration) ≤ 1 (second migration)
FDA 21 177.2600 Paragraph f (mg/sqi)	7,08	1,3	≤ 175 (first migration) ≤ 4 (second migration)

[1] Refer to OFI Formulation check No. MK-47-2022
[2] Requirements according to FDA 21 177.2600

This Test Report No. **2101803 / 15376 / 1He-k1** comprises
4 sheets, 5 tables and 0 appendix(es).

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Gerhard Kocher
Testing engineer

Christoph Wirrer
Director in charge

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