

SGS INSTITUT FRESENIUS GmbH • Postfach 1261 • 65220 Taunusstein

Anyseals NV  
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Preenaker 2-4  
BE-1785 Merchtem

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Consumer and Retail  
Non food

Taunusstein, 30/05/2017

**Test-report no. 3364419**  
**Test-report version < 1 >**

Original Sample ID	Sample Description	Sample Receipt Date
170449312	EPDM 70 black Material-No. 1270-19009	26/04/2017

**General Information**

SGS-Client's ID	:	10151372
SGS-Customer-Order	:	4141459
Ordering date	:	25/04/2017
Testing period	:	28/04/2017 – 10/05/2017
Testing scope	:	Test according to client's requirements

**Assessment**

Overall assessment	pass
The sample meets the requirements of FDA 21 § 177.2600 in the tested items.	

**SGS INSTITUT FRESENIUS GmbH**  
i. V. Dr. Nadine Paul  
(Head of Hardlines Service)  
i. A. Eleonore Niedenthal  
(Project Manager)

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**Summary of results**

Test	Result
FDA CFR 21§ 177.2600	pass

**Note:** Conclusions on pass/fail are based on the test result from the actual sampling of the received sample(s). Conclusions are based on the relevant requirements; measurement uncertainties are not taken into account. Only results above the relevant detection limit are taken into account for the calculation of sums. Test was conducted on composite of random parts of the item as per client's request and the test result is the overall result. The composite sampling method is based on the client's special request and could be a modification from the testing standard. For 2-composite mix with results exceeding one half of the relevant requirements or 3-composite mix with results exceeding one third of the relevant requirements, the composite sample may have the possibility of one or more components that can lead to a failure result, it is recommended to test on individual basis.

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**Photo documentation****List of sample parts**

Comp. no	Component-ID	Sample-Description		Original Sample ID
1		EPDM 70 black	Material-No. 1270-19009	170449312

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## Analytical results

### FDA 21 CFR 177.2600 –Extractables

#### **Test method**

21 CFR 177.2600 (e), the extractives have been determined gravimetrically

simulant	water
duration	7 hours
	followed by 2 hours
temperature	reflux

<u>Subsample(s)</u>	<u>Unit</u>	<u>Result</u>
		<u>1</u>
Water (7h)	mg/in <sup>2</sup>	< 0,5
Water (2h)	mg/in <sup>2</sup>	< 0,5
Conclusion		pass

**Requirement:** 7 hours reflux / water: max. 20 mg/in<sup>2</sup> (21 CFR 177.2600)  
2 hours reflux / water: max. 1 mg/in<sup>2</sup> (21 CFR 177.2600)

### FDA 21 CFR 177.2600 –Extractables

#### **Test method**

21 CFR 177.2600 (f), the extractives have been determined gravimetrically

simulant	n-hexane
duration	7 hours
	followed by 2 hours
temperature	reflux

<u>Subsample(s)</u>	<u>Unit</u>	<u>Result</u>
		<u>1</u>
n-hexane (7h)	mg/in <sup>2</sup>	6
n-hexane (2h)	mg/in <sup>2</sup>	1
Conclusion		pass

**Requirement:** 7 hours reflux / n-hexane: max. 175 mg/in<sup>2</sup> (21 CFR 177.2600)  
2 hours reflux / n-hexane: max. 4 mg/in<sup>2</sup> (21 CFR 177.2600)

\*\*\* End of test report \*\*\*

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