eurofins | Product Testing

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Migration Report

30 August 2019

1 Sample Information

Sample name	Novasil® S 90
Sample reception	24/10/2018
Sample no.	392-2018-00428101
Analysis period	26/10/2018 - 23/11/2018

2 Brief Evaluation of the Results

Type of analysis	Conclusion	Regulation or protocol
Extractable and volatile compounds	Pass	BfR XV
Extraction analysis	Pass	FDA 21 CFR 177.2600

Full details based on the testing and direct comparison with limit values are available in the following pages

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3 Applied Test Methods

3.1 General Test References

Method	Parameter	Analysis principle	LOD	Um(%)
12. Mitteilung des BGA, 1968, p.56 *¤[1]	Extractable compounds	Gravimetry	0.2 - 0.3 %	20 %
61. Notification BfR S.365 *¤1	Volatile compounds	Gravimetry (Weight loss after 1 hour at 100˚C)	0.1%	20 %
FDA 21 CFR §177.2600 *	Hexane extracted residue after 7 hours (and after extra 2 hours)	Gravimetry	0.1 mg/in²	20 %
FDA 21 CFR §177.2600 *	Water-extracted residue after 7 hours (and after extra 2 hours)	Gravimetry	0.1 mg/in²	20 %

4 Results

4.1 Extractables and Volatiles according to BfR XV

Parameter	Result	Limit value#
Extractable components in water	<0.2 %	0.5 %
Extractable components in 3% acetic acid	<0.3 %	0.5 %
Extractable components in 10% ethanol	<0.2 %	0.5 %
Volatile Compounds	<0.1 %	0.5 %

According to BfR recommendation XV on silicone

4.2 Extraction according to FDA CFR 177.2600

Parameter	Result [mg/in²]	Limit Value#[1] [mg/inch²]
Hexane extracted residue after 7 hours*	47	< 175
Hexane extracted residue after +2 hours*	1.5	< 4
Water-extracted residue after 7 hours*	< 0.1	< 20
Water-extracted residue after +2 hours*	< 0.1	< 1

#[1] From FDA 21 CFR 177.2600 Rubber articles intended for repeated use.

[1] Eurofins Consumer Product Testing GmbH : DIN EN ISO/IEC 17025:2005 D-PL-14435-01-00

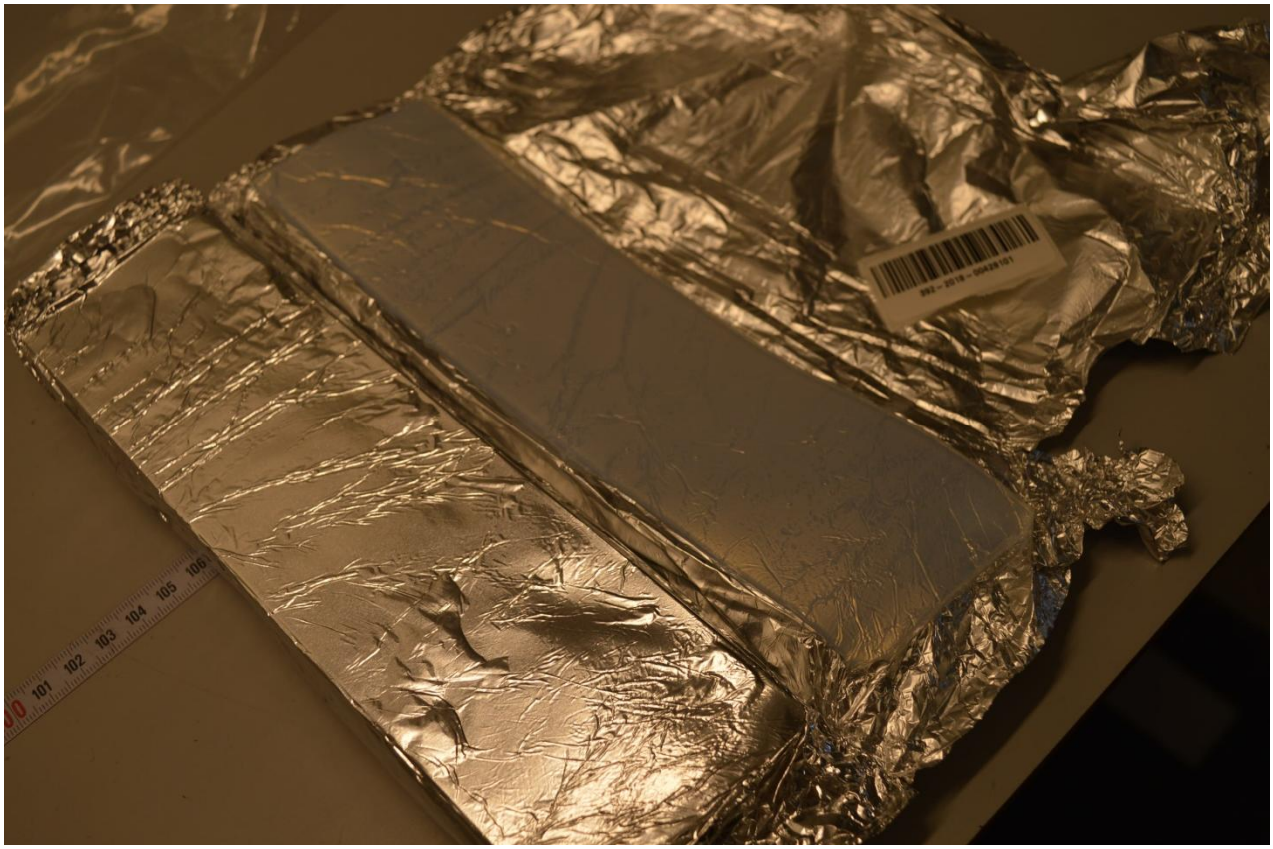
*: Not accredited
¤: Internal test method
<: Less than
n.d: Not detected
>: Greater than
n.m: Not measurable
LOD: Limit of detection
LOQ: Limit of quantification
Um(%): The expanded uncertainty Um(%) equals 2 x RSD%. For further information please visit www.eurofins.dk/uncertainty
The results are only valid for the tested sample(s).

5 Summary and Evaluation of the Results

All results for analyses performed are **below** the threshold values stated.

Consequently the product tested **complies** with the requirements in the BfR recommendation XV Silicones for the above mentioned test conditions.
Moreover the product complies with the requirements in FDA 21 CFR 177.2600 Rubber articles intended for repeated use.

6 Picture of Sample



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