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## Migration Report

23 November 2018

### 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 XXI
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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The results are only valid for the tested sample(s).

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392-2018-00428101\_MP\_EN

Page 1 of 3

### 3 Applied Test Methods

#### 3.1 General Test References

Method	Parameter	Analysis principle	LOD	Um(%)
12. Mitteilung des BGA, 1968, p.56 * <sup>1</sup>	Extractable compounds	Gravimetry	0.2 - 0.3 %	20 %
61. Notification BfR S.365 * <sup>1</sup>	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/in <sup>2</sup>	20 %
FDA 21 CFR §177.2600 *	Water-extracted residue after 7 hours (and after extra 2 hours)	Gravimetry	0.1 mg/in <sup>2</sup>	20 %

### 4 Results

#### 4.1 Extractables and Volatiles according to BfR

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 XXI on silicone

#### 4.2 Extraction according to FDA

Parameter	Result [mg/in <sup>2</sup> ]	Limit Value# <sup>1</sup> [mg/inch <sup>2</sup> ]
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

#<sup>1</sup> From FDA 21 CFR 177.2600 Rubber articles intended for repeated use.

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

\*: Not accredited

<: Less than

>: Greater than

LOD: Limit of detection

Um(%): The expanded uncertainty Um(%) equals 2 x RSD%. For further information please visit [www.eurofins.dk/uncertainty](http://www.eurofins.dk/uncertainty)

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## 5 Summary and Evaluation of the Results

All results for the 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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⌘: Internal test method

n.d: Not detected

n.m: Not measurable

LOQ: Limit of quantification