



Sika AG  
Report No. SI 1103-544

# Cleanroom<sup>®</sup> Suitable Materials

Sikafloor-325  
Particle (vs. PA6): GMP A  
Biol. Resistance: excellent

## Flooring & Coating

DUPLICATE

Statement of  
Qualification

# Statement of Qualification

**Customer:** Sika Deutschland GmbH  
Kornwestheimerstraße 103-107  
70439 Stuttgart  
Germany

**Material tested:** Sikafloor-325 RAL 7037  
Detailed test information regarding the sample (serial number, color, batch number, etc.), environment and parameters used, can be obtained from the CSM test report number SI 1103-544 issued by the Fraunhofer-Gesellschaft.

**Tests performed (in accordance with CSM procedures):**  
1) Measurement of particle emission (airborne) from material when subjected to friction  
2) Measurement of the biological resistance

**Test parameters:**  
1) Reel-on-disc test vs. PA6; normal force 300N.  
2) • Fungi test (Procedure A) using a suspension of spores and bacteria test (Procedure C) using a suspension of bacteria with the test specimens according to ISO 846.  
• Incubation at 24°C and 95 % relative humidity and visual analysis after four (4) weeks

**Test results / Classification:**  
1) The level of particulate contamination emitted during application of tribological stress on the material pairing specified lies within the permissible values of the corresponding Air Cleanliness Classes in accordance with EU-GMP Annex 1, in operation.

Material pairing	Air Cleanliness Class
Sikafloor-325 RAL 7037 vs. PA6	Suitable for GMP Class A (EU-GMP Annex 1)

2) Biological resistance

	ISO Classification (acc. to ISO 846)	CSM Classification
Fungi (Procedure A)	0	excellent
Bacteria (Procedure C)	0	excellent
<b>Overall Result</b>	<b>0</b>	<b>excellent</b>

The CSM classification according to biological resistance is based on a worst-case consideration of both procedures A and C. Therefore, the numerical classification according to ISO 846 is transferred in following CSM classification:

0 = excellent      3 = weak  
1 = very good      4 = very weak  
2 = good            5 = none

**Standards used for the qualification:** EU-GMP Annex 1; ISO 846; VDI 2083 Part 18  
Each standard stated refers to the version valid at the time of testing.

**Test environment:**  
1) Cleanroom fulfilling Air Cleanliness Class ISO Class 1 Specifications (in accordance with ISO 14644-1);  
Vertical unidirectional air flow from ceiling to floor,  
Air flow velocity: 0.45 m/s; Temperature: 71.6°F ± 0.9°F,  
Relative humidity: 45 % ± 5 %  
2) Microbiological S2 laboratory

**Declaration:** The measuring equipment used for the qualification is regularly calibrated and is based on national and international standards. In the case where no national standards exist, the measuring procedure used corresponds with technical regulations and norms valid at the time of the measurement. The documents drawn up for this procedure are available for viewing.

The validity of this statement is temporary indefinite and limited to the named product. It can be verified under [www.tested-device.com](http://www.tested-device.com). For more CSM information, visit our website at [www.ipa-csm.com](http://www.ipa-csm.com).

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