Cleanroom® Suitable Materials

Sika AG
Report No. SI 1008-533

Sika-ComfortFloor
Particle (vs. PA6): GMP A
Biol. Resistance: very good

Flooring & Coating

Statement of Qualification

Fraunhofer IPA

Fraunhofer IPA

Statement of Qualification

Customer:

Sika Deutschland GmbH
Kornwestheimerstraße 103-107
70439 Stuttgart
Germany

Material tested:

Sikafloor ComfortFloor
- Wearing course: Sikafloor-330
- Seal coat: Sikafloor-505 W RAL 7035

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 1008-533 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 300 N.
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 EC-GMP Annex 1, in operation.

Material pairing	Air Cleanliness Class
Sikafloor ComfortFloor vs. PA6	Suitable for GMP Class A (EC-GMP Annex 1)

2) Biological resistance

	ISO Classification (acc. to ISO 846)	CSM Classification
Fungis (Procedure A)	0	excellent
Bacteria (Procedure C)	1	very good
Overall Result	**1**	**very good**

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 transfered in following CSM classification:

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

Standards used for the qualification:

EC-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.
For more CSM information, visit our website at www.ipa-csm.com.

Fraunhofer Institute
for Manufacturing Engineering
and Automation (IPA)

Department Ultraclean Technology
and Micromanufacturing

Nobelstrasse 12
70569 Stuttgart
Germany

Stuttgart, May 11, 2011
Place, date

i. A.
Project manager