Fraunhofer Institute for Manufacturing Engineering and Automation IPA

Director
Prof. Dr.-Ing. Thomas Bauernhansl
Prof. Dr.-Ing. Alexander Sauer

Nobelstrasse 12
70569 Stuttgart

Phone + 49 711 970-00 | Fax -1399
www.ipa.fraunhofer.de

Test report

Cleanroom suitability tests on materials

Customer:	Gerflor Mipolam GmbH Mülheimer Strasse 27 53840 Troisdorf Germany
Project Manager:	Dr.-Ing. Udo Gommel
Report No.	**GE 2105-1233**

Stuttgart, Germany, September 20, 2021

1 Index

2 Introduction and objectives

Gerflor is an established manufacturer of chemistry and industrial materials. The components are produced under high quality requirements and are successfully implemented in a wide range of industries.

To secure the market position of Gerflor in the sector of cleanroom technology, the aim is to identify optimization potentials for its products. The suitability of a product for use in clean areas is significantly influenced by the materials used in its manufacture.

The industrial alliance "Cleanroom Suitable Materials CSM" has developed procedures for determining the cleanroom suitability of materials. Depending on the area of implementation concerned, the behavior of materials with regard to particle emission is taken into consideration. The tests are carried out in a standardized way in compliance with relevant national and international norms.

The results obtained provide an objective and substantiated basis for comparison and can be referred to when selecting suitable materials for specific manufacturing environments and areas of implementation. In consequence, this improves the cleanroom suitability of the respective products.

3 Materials tested

TP01	
Description of test piece	Mipolam Biocontrol Clean
Description of test piece (short form)	Mip. Biocontrol Clean
Company name	Gerflor
Color	Gray 5430
Manufacturing date	2/5/2021
Charge number	VB01
Surface	Slightly structured

Figure 1 Overview of materials tested

	Particle Emission	Outgassing Behavior	Riboflavin Test	Chemical Resistance	Biological Resistance	Antibacterial activity	H_2O_2 Absorption/Desorption
TP01	X	X	X	X	X		X

Figure 2 Overview of tests performed

4 Overview of results

Particle emission (CSM classification/VDI 2083 Part 17 according to ISO 14644-1)			
Material pairing			**ISO Class**
Specimen	**Counter specimen**	**Lubricant**	
Mip. Biocontrol Clean	PA6 Nylon	(none)	**3**

Outgassing VOC/SVOC (CSM classification/VDI 2083 Part 17 according to ISO 14644-8)			
Material	**Temperature**	**Tested for**	**ISO-ACC$_m$ Class**
Mip. Biocontrol Clean	23 °C	VOC	**-8.2**
		SVOC	**< -9.6**
Material	**Temperature**	**Tested for**	**Surface specific emission rate**
Mip. Biocontrol Clean	90 °C	VOC	**9.4×10^{-6}**
		SVOC	**9.3×10^{-7}**
		Amines	**$< 1.7 \times 10^{-9}$**
		Organophosphates	**$< 1.7 \times 10^{-9}$**
		Siloxanes	**3.9×10^{-9}**
		Phthalates	**$< 1.7 \times 10^{-9}$**

Outgassing acids and bases (CSM classification/VDI 2083 Part 17 according to ISO 14644-8)			
Material	**Temperature**	**Tested for**	**ISO-ACC$_m$ Class**
Mip. Biocontrol Clean	23 °C	NH_3	**< -8.5**
		HF	**< -8.5**
		HCl	**< -8.5**
		HBr	**< -8.5**
		HNO_3	**< -8.5**
		H_3PO_4	**< -8.5**
		H_2SO_4	**< -8.5**
Mip. Biocontrol Clean	90 °C	NH_3	**< -8.5**
		HF	**< -8.5**
		HCl	**< -8.5**
		HBr	**< -8.5**
		HNO_3	**< -8.5**
		H_3PO_4	**< -8.5**
		H_2SO_4	**< -8.5**

Riboflavin test (VDMA information sheet)					
Material	**Surface**	**Test 1**	**Test 2**	**Test 3**	**Overall result**
Mip. Biocontrol Clean	Slightly structured	3	3	3	**weak**

Chemical resistance (CSM classification/VDI 2083 Part 17 according to ISO 4628)				
Material	**Technique**	**Chemicals**	**Single result**	**Overall result**
Mip. Biocontrol Clean	Immersion	Formalin (37%)	excellent	**excellent**
		Ammoniac (25%)	excellent	
		Hydrogen peroxide (30%)	excellent	
		Sulfuric acid (5%)	excellent	
		Phosphoric acid (30%)	excellent	
		Peracetic acid (15%)	very good	
		Hydrochloric acid (5%)	excellent	
		Isopropanol (100%)	very good	
		Sodium hydroxide (5%)	excellent	
		Sodium hypochlorite (5%)	excellent	

Biological resistance (CSM classification according to ISO 846)			
Material	**Technique**	**Single result**	**Overall result**
Mip. Biocontrol Clean	Procedure A (fungi)	weak	**weak**
	Procedure C (bacteria)	excellent	

H_2O_2 absorption/desorption (CSM classification according to VDI 2083 Part 20)			
Material	**Ø k-value**	**Standard deviation**	**Overall result**
Mip. Biocontrol Clean	2.1	0	**non-absorptive**

Figure 3 Overview of results obtained

5 Airborne particle emission tests on application with tribological stress according to CSM classification and VDI 2083 Part 17

5.1 Procedure for particle emission tests

5.1.1 Cleanroom-suitable material test bench

A special, cleanroom-suitable material test bench developed by Fraunhofer IPA and called "Material Inspec" is used for the tests. The test bench enables material pairings to be subjected to controlled tribological stress and permits the resulting particulate emissions to be measured without the influence of any cross-contamination.

Figure 4 Cleanroom-suitable material test bench "Material Inspec" developed by Fraunhofer IPA with module for ball on disk test. The module can be replaced if necessary with the module for reel on disc test.

Tribological stress

The cleanroom-suitable material test bench "Material Inspec" enables tests to be carried out using the tribological methods known as **reel-on-disk** and **ball-on-disk** tests.

With the **reel-on-disk test**, a reel with a **normal force F** is pressed onto the surface of a disk rotating with the **frequency f**. The reel is not fixed, enabling it to roll across the surface of the disk. The width of the reel causes a line-shaped contact point to be formed; the single **test distance s** (= circumference with known **radius r**) and **relative velocity v** vary over the course of this line.

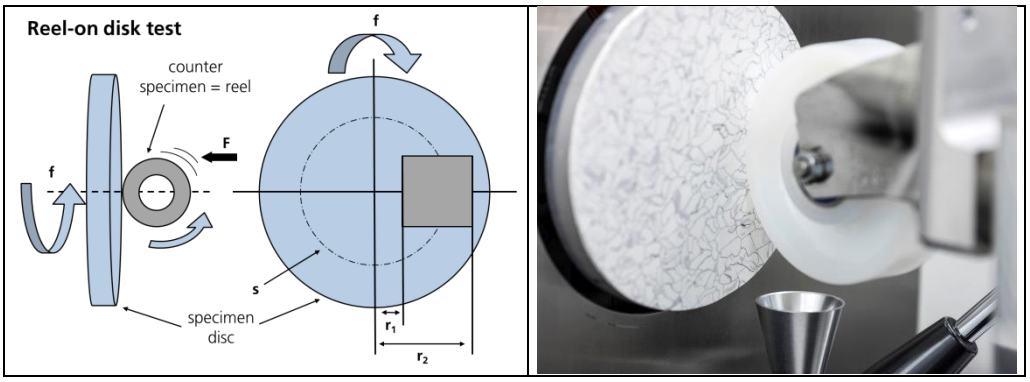


Figure 5 Tribological stress on material pairing – principle of reel-on-disk test

The reel-on-disk test is especially suitable for simulating **stress on floor coverings due to movable devices** (e.g. trolleys). Test conditions are very similar to those experienced by the test piece in reality.

All of the tests which are carried out are model tests. This means that the forces mentioned or applied are similar to but may not be exactly the same as those encountered in reality. This fact requires special consideration when interpreting the results and transferring them to real components.

5.1.1.1 Force transmission and measurement recordings

The normal force is applied using a force transmission unit. For the reel-on-disk test, steel springs are utilized because of the increased forces. The **normal force** applied is recorded continuously during the test using a load cell based on the principle of the strain gauge.

Particle measurement

Particulate emissions are measured directly beneath the point of contact of the material test specimen. In the case of the reel-on-disk test, because of the broader line-shaped contact, a cylindrical particle probe with an aperture of 35 mm in diameter is used.
The area of contact has been specially designed from an airflow point of view to ensure that the majority of particles emitted are detected.

Particle emissions are measured continuously during the tests with a measuring interval of 6 seconds (determined by the device used).

5.1.1.2 Test parameters

For the reel-on-disk tests, the essential test parameters affecting particulate emission include the **single measuring track s**, the **relative velocity v**, the **normal force F** and the **number of revolutions N**. Standardized sets of stress parameters are formed using these values to facilitate the comparison of results obtained from the various tests.

Note that with the reel-on-disk test the values stated for the single test distance and relative velocity refer to the center of the line-shaped contact area between the reel and the disk.

Set of parameters	s [mm]	v [mm/s]	F [N]	N
B01	250	150	15	1500
B02	250	150	45	1500
B03	250	150	75	1500
B04	250	150	90	1500
B05	250	150	120	1500
B06	250	150	150	1500
B07	250	150	165	1500
B08	250	150	195	1500
B09	250	150	225	1500
B10	250	150	240	1500
B11	250	150	270	1500
B12	250	150	300	1500

Figure 6 Defined set of stress parameters; reel-on-disk test

The amount of stress to be applied to each material pairing is decided upon individually by Fraunhofer IPA on taking into account the quantity of particles generated and the measuring range of the device used in the test.

The following table shows the degree of accuracy achieved when setting the test parameters as well as fluctuations in these parameters which are experienced during the tests.

	Accuracy; maximum variation during test
	Reel-on-disc-test
Normal force F	0.01 N; +/- 3 %
Single measuring track s	0.1 mm; n.a.
Relative velocity v	0.5 mm/s; +/- 3 %
Number of revolutions N	+/- 1 %

Figure 7 Degree of accuracy achieved when setting the test parameters and fluctuations thereof during the test

5.1.2 Cleanroom environment

All tests are carried out at the Fraunhofer IPA Competence Center for Ultraclean Technology and Micromanufacturing. Measurements are taken in a cleanroom fulfilling Class 1 specifications (in accordance with ISO 14644-1). A vertical, unidirectional airflow prevails in the cleanroom with a first air flow velocity of 0.45 m/s. Environmental conditions are kept constant with a room temperature of 22 °C ± 0.5 °C and a relative humidity of 45 % ± 5 %.

In compliance with ISO 14644-1, Cleanroom "Class 1" means that only two particles the size of 0.2 µm may be found in a reference volume of one cubic meter in the first air (filtered air introduced into the cleanroom). In practical operation, even fewer particles are found in this class.

5.1.3 Particle measuring technique

Optical particle counters are utilized to determine particle emission during the tests.

Optical particle counters function according to the theory of scattered light. Using a sampling probe, a defined volume of air of 1 cubic foot (1 cft = 28.3 liters) is sucked in per minute and guided into a measuring chamber via a tube connected to it. The air sucked in is illuminated by a laser beam. As soon as a particle carried by the airflow is hit by a light ray, the light is scattered and recorded by photo-detectors.

The amount of impulses registered equates to the number of particles found in the volume of air; the height of the impulse gives an indication of particle size.

Depending upon the size and amount of particles generated, the following measuring device is used.

Model	Company	Particle sizes detected
LasAir II 110	PMT AG, Heimsheim	0.1 / 0.2 / 0.3 / 0.5 / 1.0 / 5.0 µm

Figure 8 Optical particle counters used to record particle emissions

The volume of air sucked in by the device is 1 cft/min = 28.3 l/min.
In order to obtain a chronological progression of the particles emitted, particle measurements are recorded every 6 seconds.

5.1.4 Test procedure

The test specimens are **introduced** into the cleanroom before the tests are commenced. In the process, the surfaces of the test pieces and a new reel (for each test series) are cleaned to remove any sedimented particles or filmy contamination which may be present.

Before the actual test is performed, the reel is first run in using an initial sample in order to remove any contamination from the reel resulting from the manufacturing process. Of course, the results of this pre-test are rejected and not included in the assessment.

Where possible, the **tribological test** is carried out using **one set of stress parameter**, taking into account the quantity of particles generated. To ensure reliability of the results, **10 repeated tests** are carried out for each set of stress parameter.

5.2 Material samples for particle emission tests

Tested materials					
ID[1]	Specimen	Typ of load	Counter specimen	Lubricant	Load
IP Gerflor 12	Mipolam Biocontrol Clean	Reel-on-disk-test	PA6 Nylon	(none)	B12

Figure 9 Materials for the particle emission tests

For the material pairing IP Gerflor 12, a floor covering founded on a 15 mm thick disk with and a diameter of 140 mm is used as a specimen.
A reel with a width of 60 mm and a diameter of 100 mm, made of PA6 Nylon, is used as counter specimen.

[1] Material identifier used within this report.

Photographs of the materials tested:

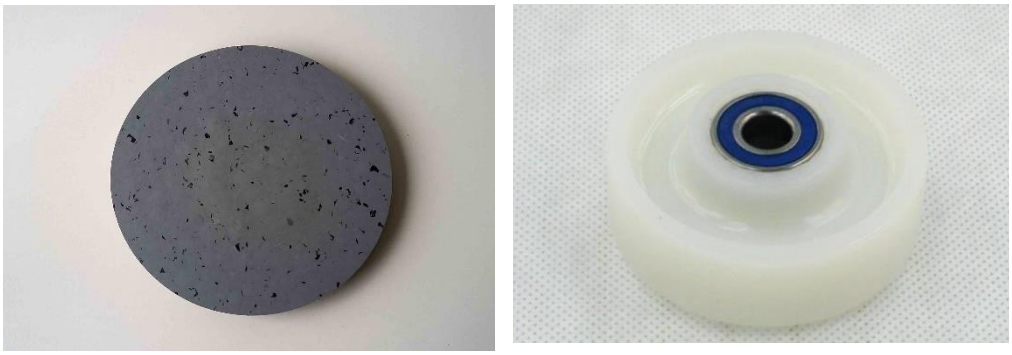


Figure 10 Materials tested – left: Mipolam Biocontrol Clean; – right: PA6 Nylon

5.3 Particle emission results

5.3.1 Differential progression of particle emission

5.3.1.1 Method

Particle emission is measured every 6 seconds during the application of tribological stress. Depending upon the particle counter used, particle emission is classified into various **particle size channels**. The values measured are expressed **cumulatively**, i.e. the result for one size always includes all particles equal to or larger than the reference size for that channel. For example, the information obtained for the particle size 0.1 µm includes all particles with a diameter of 0.1 µm or larger.

Each diagram shows the progression of particle emission measured in the smallest particle size channel for the ten repeated tests on application of one set of stress parameters. Where appropriate, the **scale of the y-axis** is adjusted, please note that the scale may vary from one graph to another!

5.3.1.2 IP Gerflor 12: Mipolam Biocontrol Clean versus PA6 Nylon

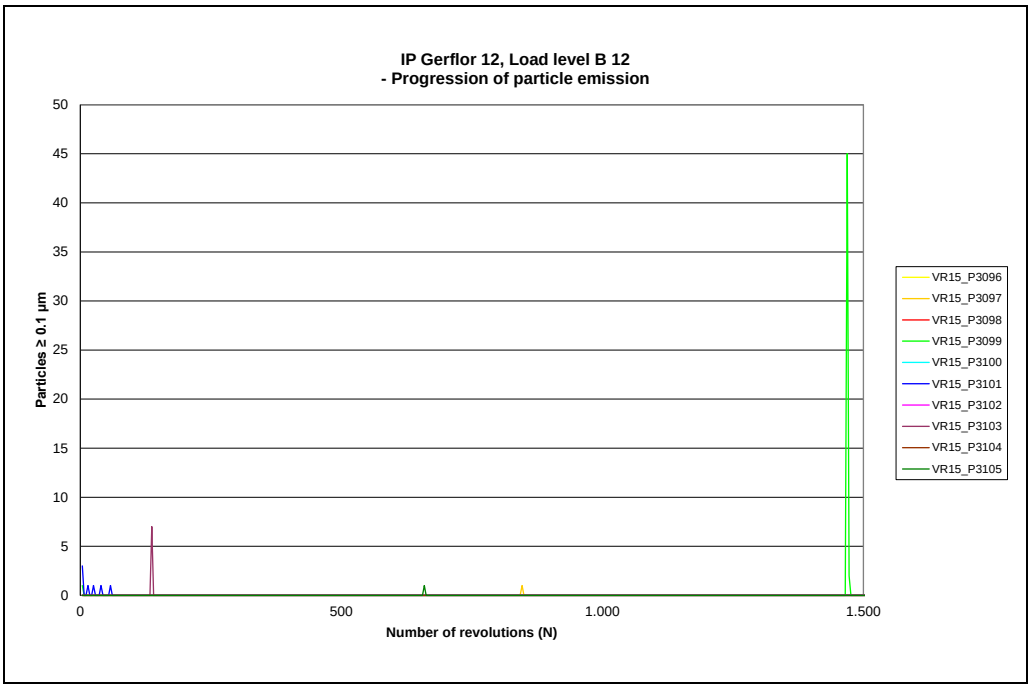


Figure 11 IP Gerflor 12 – progression of particle emission, particle size 0.1 µm, set of stress parameters B12

5.3.2 Size distribution of the emitted particles

5.3.2.1 Measurement Method

From the particle emission progression data, the percentage of each particle size in relation to the total count of emitted particles is calculated. If, for example, the particle sizes 0.1 µm, 0.2 µm, 0.3 µm, 0.5 µm, 1.0 µm and 5.0 µm are recorded by the optical particle counter, the percentage of the

- Particles in the size channel 0.1 µm relates to particles with a diameter of 0.1 µm to 0.2 µm,
- Particles in the size channel 0.2 µm relates to particles with a diameter of 0.2 µm to 0.3 µm,
- Particles in the size channel 0.3 µm relates to particles with a diameter of 0.3 µm to 0.5 µm,
- Particles in the size channel 0.5 µm relates to particles with a diameter of 0.5 µm to 1.0 µm,
- Particles in the size channel 1.0 µm relates to particles with a diameter of 1.0 µm to 5.0 µm,
- Particles in the size channel 5.0 µm relates to particles with a diameter equal to or greater than 5.0 µm.

Values are obtained from all ten repeated tests. The size channel stated is dependent upon the optical particle counter used in the tests.

In order to ensure reliability of the data, only those percentages of particles are calculated where a minimum of 100 particles was observed in the smallest size channel in the course of the entire test.

The following diagrams show the particle size distribution for the material pairings and the corresponding sets of stress parameters. If data is absent in the diagram, this means that the required minimum count of 100 particles was not recorded in the smallest size channel.

5.3.2.2 IP Gerflor 12: Mipolam Biocontrol Clean versus PA6 Nylon

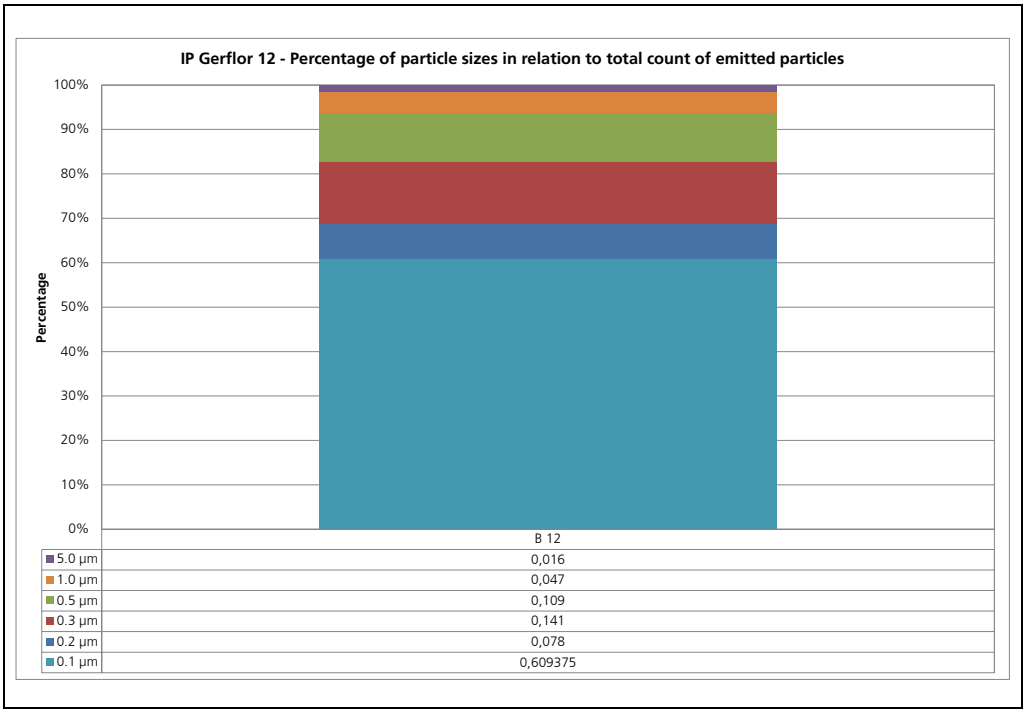


Figure 12 IP Gerflor 12 – required minimum count of 100 particles was not recorded

5.3.3 Classification according to CSM classification and VDI 2083 Part 17

5.3.3.1 Method

In general, airborne particulate contamination is the main issue considered when assessing cleanroom suitability. The most important aspects of this are the size and concentration of airborne particles. Relevant standards state limiting values for the concentration of airborne particles in dependence upon particle size, as found in ISO 14644-1. This norm describes the quality of cleanrooms using Air Cleanliness Classes ranging from 1 to 9. The lowest class, Class 1, fulfills the highest requirements with regard to air cleanliness; the limiting value of particles permitted increases with each successive cleanroom class. Calculations can be made for limiting values of any particle size between 0.1 µm and 5.0 µm for all classes using the method for calculating permitted limiting values as described in ISO 14644-1. The norm states the maximum permitted number of particles of each size for the reference volume (in this case: 1 m^3).

The tests performed record particle emissions generated when tribological stress is applied to material pairings. The amounts of particles measured are dependent upon the material pairing concerned and the set of stress parameters applied. In order to better appreciate the differences, Fraunhofer IPA has developed a method which enables classifications to be made based on the measurement results obtained using the procedure stated in ISO 14644-1.

In accordance with the procedure laid down in ISO 14644-1 for determining the permitted particle concentration of different Air Cleanliness Classes, limiting values are ascertained for the given particle size classes taking the test conditions into consideration. The limiting value is obtained from the test volume of air (sampling time multiplied by the particle counter's constant volume flow of 28.3 l/min) and the permitted particle concentrations (particles/m^3) for the corresponding Air Cleanliness Class and particle size. A comparison of these limiting values with the total counts of emitted particles gives the classification figure for the test. The calculation method has been extended to include particles sized between 0.1 µm and 25.0 µm.
Care is to be taken when comparing the classification figures; consideration of the particle size in relation to the values and also of the set of parameters applied in the respective test.

Then repeat measurements are carried out on each material pairing. This figure is used in the corresponding tables and diagrams.
The following tables show the classification figures obtained for the material pairing. The availability of classification figures for the various particle sizes depends upon the resolution of the optical particle counter used.

5.3.3.2 Overview of classification results

Mipolam Biocontrol Clean							
Load level	Normal force	Detected particle size					
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
B12	300 N	1.2	1.4	1.7	1.9	2.0	3.0
						Classification relevant to documents:	3

Figure 13 IP Gerflor 12: Mipolam Biocontrol Clean versus PA6 Nylon
Overview of classification value attained in accordance with ISO 14644-1

The level of particulate contamination emitted during application of tribological stress on the material pairing **Mipolam Biocontrol Clean versus PA6 Nylon** lies within the permissible values of the corresponding Air Cleanliness Class **ISO Class 3** in accordance with ISO 14644-1.

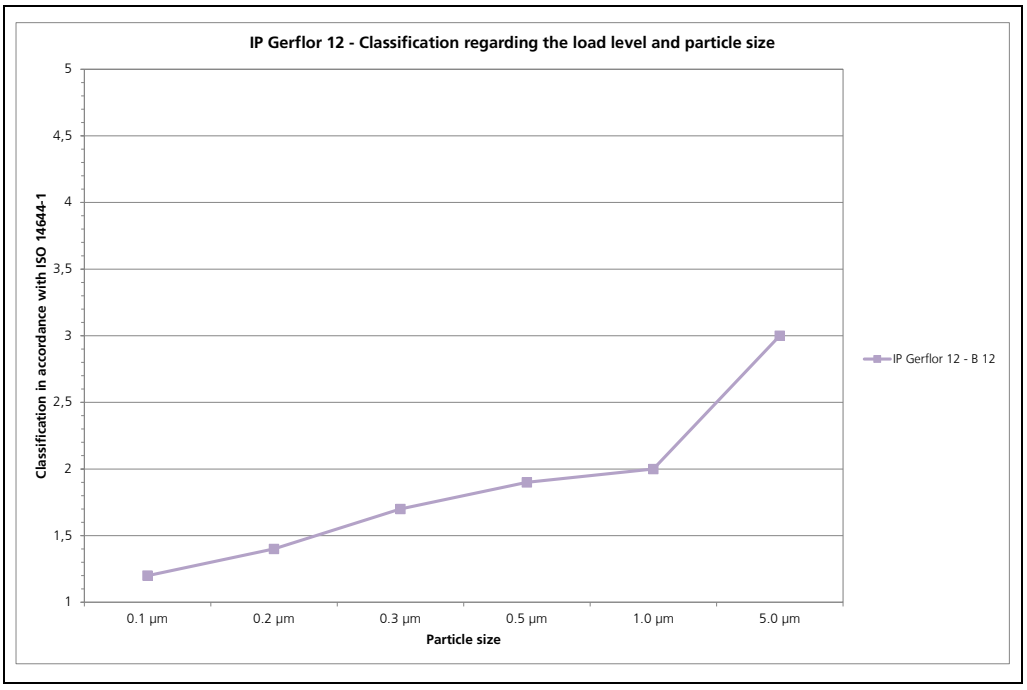


Figure 14 IP Gerflor 12: Mipolam Biocontrol Clean versus PA6 Nylon
Classification in accordance with ISO 14644-1 in dependence upon the particle size

6 Material outgassing tests – ammonia, inorganic acids and VOC/SVOC

6.1 Material samples

The material samples required for the test were supplied by the customer. Solid samples were wrapped in aluminum foil to prevent their condition from changing in any way during transport.

On arrival at Fraunhofer IPA, the samples were prepared for the outgassing tests. The weight, volume, and active surface area of the samples were ascertained. Two samples were used in each test.

The samples were stored in a minienvironment with a low VOC level at 22 °C and 45 % relative humidity.

Figure 15 Materials tested

6.2 Test procedure

6.2.1 Emission chamber (µCTE)

The test setup is based on ISO 14644-15: Closed design. The outgassing chamber (µCTE; MARKES Inc., hermetically sealed and temperature controlled) is continuously purged with ultra-pure nitrogen. The blank value of the system is determined by feeding ultra-pure nitrogen into the empty chamber.

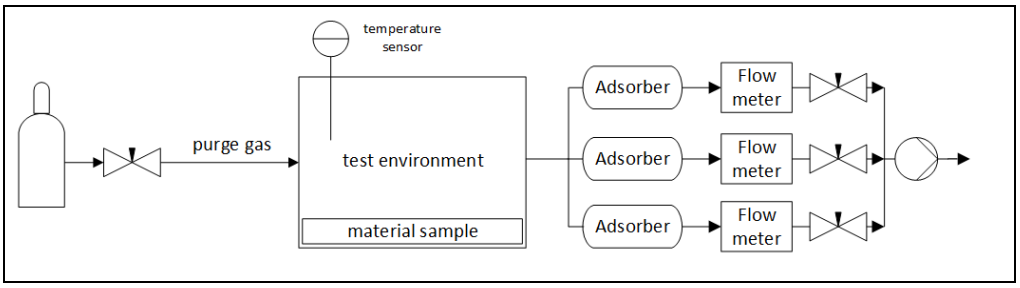


Figure 16 Diagram of the test set-up

Parameters of emission chamber	
Preconditioning time	> 5 min
Purge and sample gas flow rate	100 mL/min
Volume of emission chamber	45 cm^3

Figure 17 General parameters

6.3 Sampling (acids and bases)

The following figure shows the set-up used to assess the gaseous concentration of ammoniac as well as the inorganic acids hydrofluoric acid, hydrochloric acid, hydrogen bromide, sulphuric acid, nitric acid and phosphoric acid.
The substances outgassing from the samples are transfered with the aid of ultra-pure nitrogen to a gas wash bottle filled with adsorber solution (according VDI 2452 Sheet 1 and VDI 3496 Part 1).

Sampling temperature	23 °C	90 °C
Sampling flow rate	100 mL/min	
Sampling time	24 h	

Figure 18 Test parameters

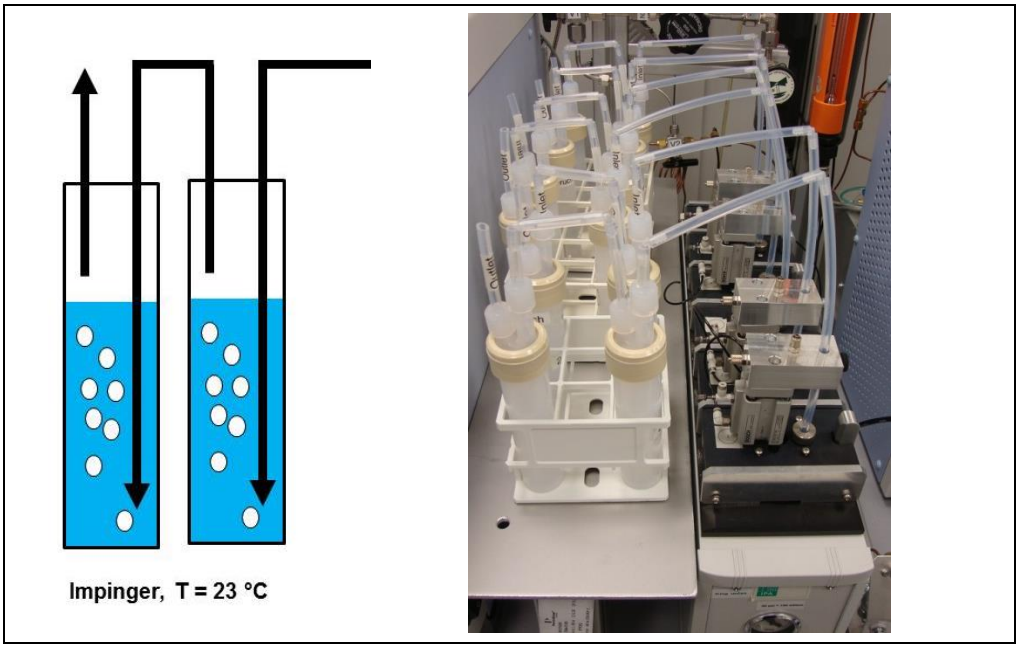


Figure 19 Diagram and photo of the set-up for measuring the emission of acids and bases (micro emission chamber)

6.4 Sampling (VOC/SVOC)

The outgassing **V**olatile **O**rganic **C**ompounds (VOC) and **S**emi **V**olatile **O**rganic **C**ompounds (SVOC) are collected by a Tenax TA adsorber tube according to ISO 16000-6. To detect the potential presence of any critical substances, forced outgassing is performed using a temperature ramp from 23 - 90 °C for 8 min and a hold time of 2 min at 90 °C.

Temperature of emission chamber	23 °C	90 °C
Sampling flow rate	100 ml/min	
Sampling time	60 min	10 min

Figure 20 Test parameters

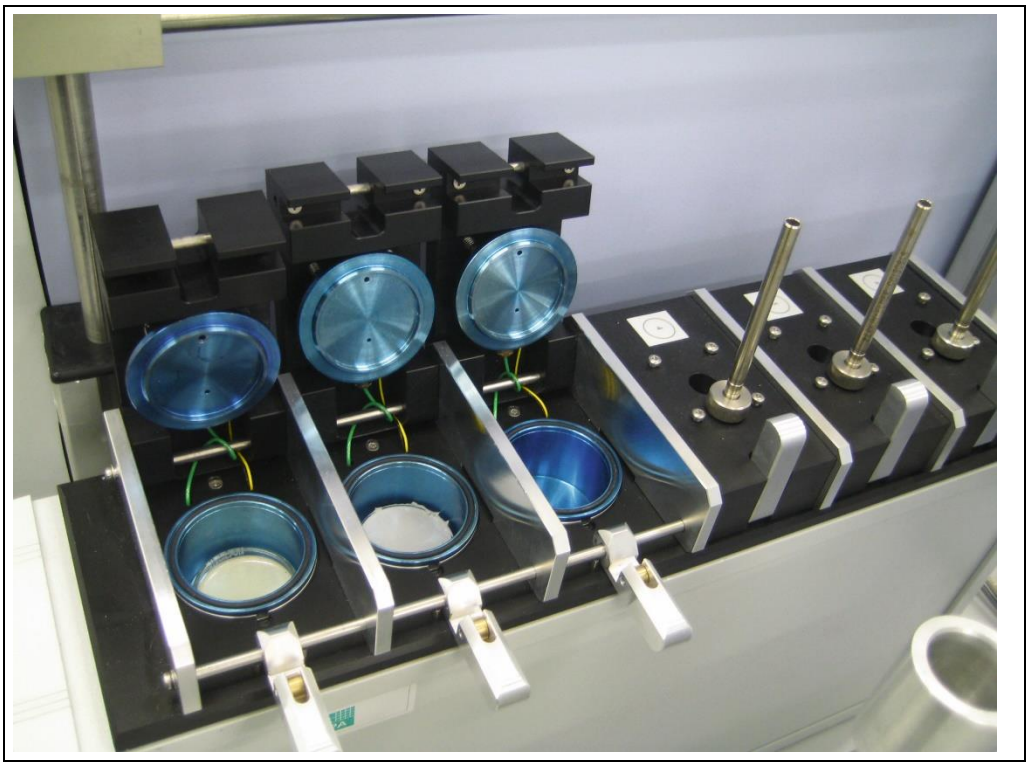


Figure 21 Photo of set-up for measuring VOC and SVOC emissions (emission chamber)

6.5 Analysis (acids and bases)

6.5.1 Inorganic acids

The inorganic acids nitric acid, sulphuric acid, phosphoric acid, hydrofluoric acid, hydrochloric acid, and hydrogen bromide (expressed as: HNO_3, H_2SO_4, H_3PO_4, HF, HCl and HBr) dissociate in water to form their corresponding anions. These anions are analyzed by ion chromatography (IC) according to ISO 10304-1.

6.5.2 Analysis of ammonia

The outgassed ammonia (NH_3) dissociates completely in the adsorber solution (1.7 mmol/L HNO_3) to form the ammonium ions (NH_4^+). The concentration of ammonium in the impingement solution is analyzed by ion chromatography (IC) according to ISO 14911.

6.5.3 Analysis device

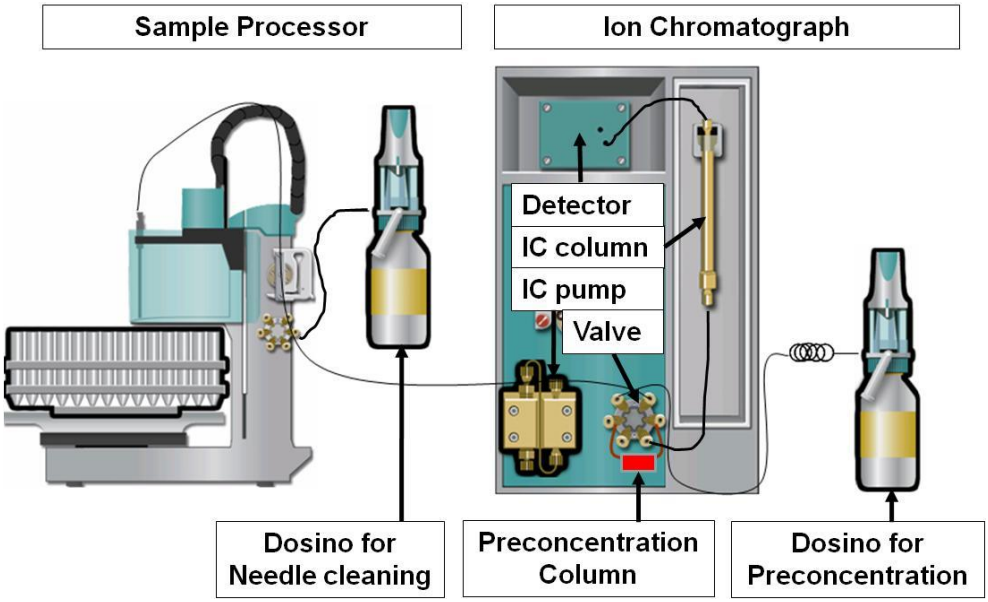


Figure 22 IC method – overview of analysis steps

- Measuring station:
  a) Metrohm Proferssional IC 850
  b) Metrohm Professional Sample Processor 858
  c) Metrohm Dosino 800
- Column temperature: 40 °C
- Software: Metrohm MagIC-Net

Anions:

- Analytical column: Metrosep A Supp 5-250 4.0 with Metrosep A Supp 5 Guard 4.0
- Preconcentration column: Metrosep A PCC 1 HC 4.0
- Eluent: Standard eluent
- Flow: 0.7 ml/min, isocratic
- Analyzed volume: 4000 µl
- Detection technique: suppressed direct conductivity detection

Cations:

- Analytical column: Metrosep C4 -150 4.0 with Metrosep C4 Guard
- Preconcentration column: Metrosep C PCC 1 HC
- Eluent: Standard Eluent
- Flow: 0.9 ml/min, isocratic
- Analyzed volume: 300 µl (dead volume of preconcentration colum)
- Detection technique: direct conductivity detection

Hardware manufactured by Metrohm AG, Herisau, Switzerland.

6.5.4 LLOQ (Lower Limit of Quantification)

According to the lower limit of quantification (LLOQ) of the IC measurement system of 10 µg/l, the following minimal area-specific emission rate SER_a can be determined:

Measurement temperature	**[°C]**	**23**	**90**
Sampling time	[h]	24	24
LLOQ of area-specific emission rate SER_a	[g/m²s]	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}
Best quantifiable ISO-ACC_m Class (according to VDI 2083 Sheet 17)	**[--]**	**-8.5**	**--**

Figure 23 LLOQ of the area-specific emission rate

6.5.5 Interpretation of chromatograms (theory acids and bases)

The different cations and anions elute from the IC system at specific retention times. The retention time is shown on the x-axis. The respective integrated area of a peak correlates to the concentration of the substance.

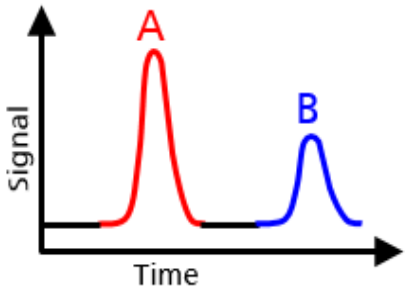


Figure 24 Exemple of a chromatogram

6.6 Analysis (VOC/SVOC)

The adsorber tube containing the outgassed substances is analyzed using an ATD-GC/MS unit (thermodesorption gas chromatography in combination with mass spectrometry) according to ISO 16000-6.

6.6.1 Analysis device

GC/MS:	a) GC: PerkinElmer Clarus 600 b) MS: PerkinElmer Clarus SQ8
Thermodesorber:	PerkinElmer Turbomatrix ATD 650
Column:	PerkinElmer Elite 5 – MS, l = 60 m, ID = 0.25 mm, film = 0.25 µm

6.6.2 LLOQ (Lower Limit of Quantification)

According to the lower limit of quantification of the measurement system (LLOQ) of 1 ng absolute mass, the following minimal outgassing rate (area-specific emission rate SER_a) can be determined:

Measurement temperature	**[°C]**	**23**	**90**
Sampling time	[min]	60	10
LLOQ of area-specific emission rate SER_a	[g/m²s]	2.8×10^{-10}	1.7×10^{-9}
Best determinable ISO-ACC_m Class (VOC/SVOC)	**[--]**	**-9.6**	**--**

Figure 25 LLOQ of the area-specific emission rate

Only the measurement at 23 °C is used for material classification. The 90 °C measurement (forced outgassing) is used to determine the potential presence of critical compounds.

6.6.3 Interpretation of chromatograms (theory VOC/SVOC)

The different VOCs and SVOCs elute from the IC system at specific retention times. The retention time is shown on the x-axis. The respective integrated area of a peak correlates to the concentration of the substance to toluene.

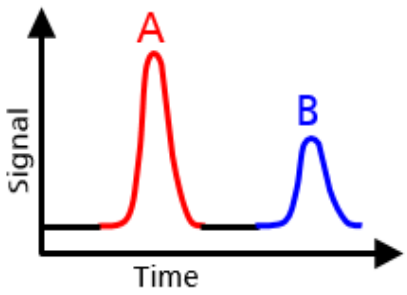


Figure 26 Exemple of a chromatogram

Note:
Based on the detailed results, conclusions can be drawn about the composition of the tested material.

To identify this, the mass spectrum obtained is compared with a database (NIST database). If a substance cannot clearly be identified with the NIST database, this is noted accordingly in the sample list.

A semi-quantitative determination of all signals is carried out in relation to an external standard toluene-D8.

6.7 Theory of classification

The classification is based on the guideline VDI 2083 Sheet 17. The material-specific classification (ISO-ACC_m class) is calculated as the common logarithm of the determined area-specific emission rate SER_a, expressed in g/m^2s. By using logarithmic calculus, the ISO-ACC_m classes feature all negative values with the result that permissible concentrations decrease as quantities increase. Therefore, ISO-ACC_m Class -12 equates to an emission value 1000 times lower than ISO-ACC_m Class -9.

The ISO-ACC_m class obtained states that 1 m^2 of the tested material emits a quantity of the given substance class over a period of 1 s at the test temperature which, when related to the reference volume of 1 m^3, is within the permissible concentration for this class as described in ISO 14644-8. The reference volume must be constant in order to convert the obtained values to real cleanrooms (see VDI 2083 Sheet 17).

Only the measurement at 23 °C can be used for classification purposes. The measurement at 90 °C (total outgassing) is only used to determine the potential presence of critical compounds.

Remark: ISO 14644-8 addresses the classification of cleanrooms based on the concentration of certain groups of contaminants (ISO-ACC classes). The contaminant groups can be volatile organic compounds (VOC), organic (or) acids (ac) and/or bases (ba), dopants (dp) or others, and are expressed with the corresponding descriptor.

6.8 Results (acids and bases)

6.8.1 Ammonia

6.8.1.1 Measurement at 23 °C

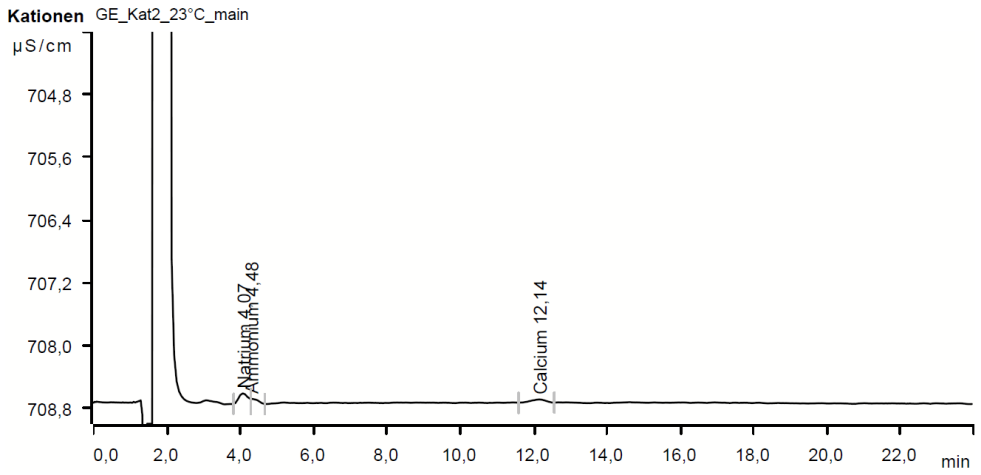


Figure 27 Chromatogram of the sample measurement at 23 °C

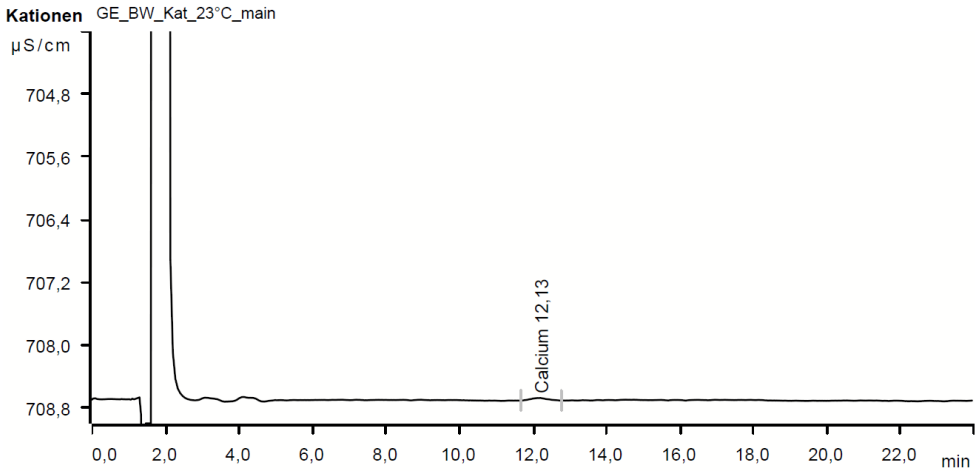


Figure 28 Chromatogram of the blank value at 23 °C

The measured values are below the quantification limit. No outgassing of NH_3 and could be quantified.

6.8.1.2 Measurement at 90 °C

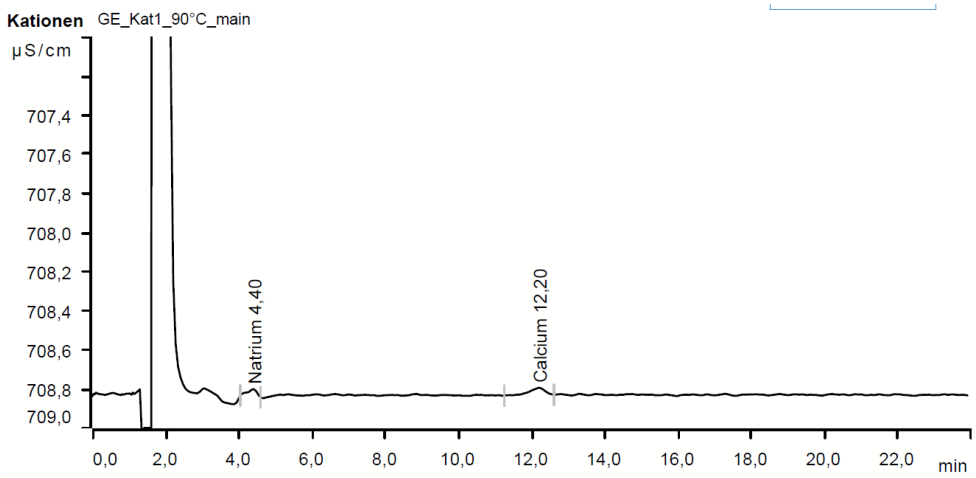


Figure 29 Chromatogram of the sample measurement at 90 °C

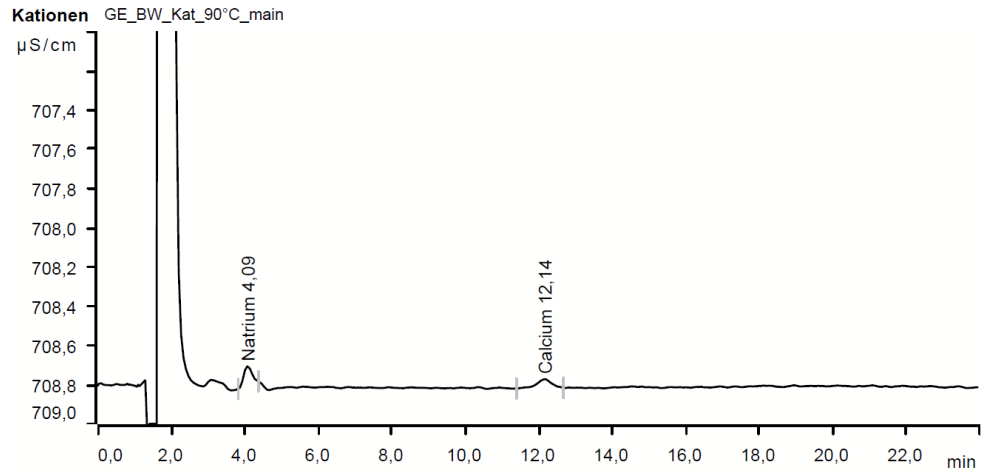


Figure 30 Chromatogram of the blank value at 90 °C

The measured values are below the quantification limit. No outgassing of NH_3 could be quantified.

6.8.2 Inorganic acids

6.8.2.1 Measurement at 23 °C

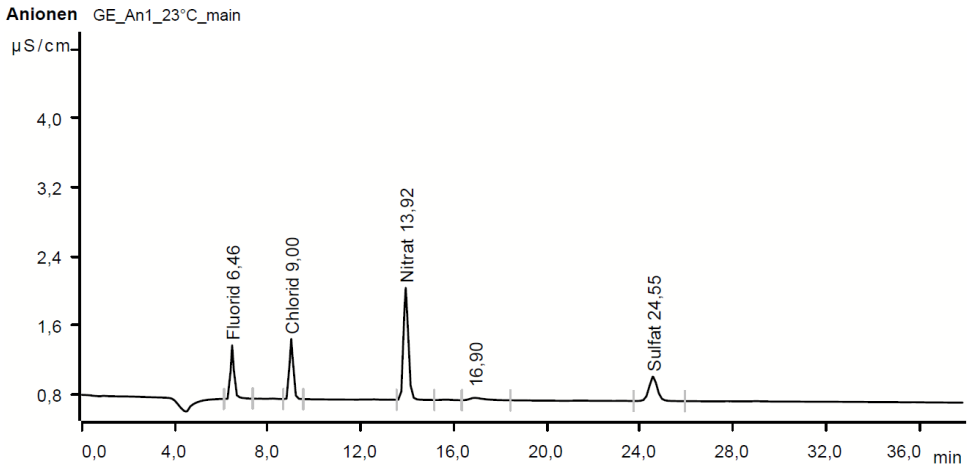


Figure 31 Chromatogram of the sample measurement at 23 °C

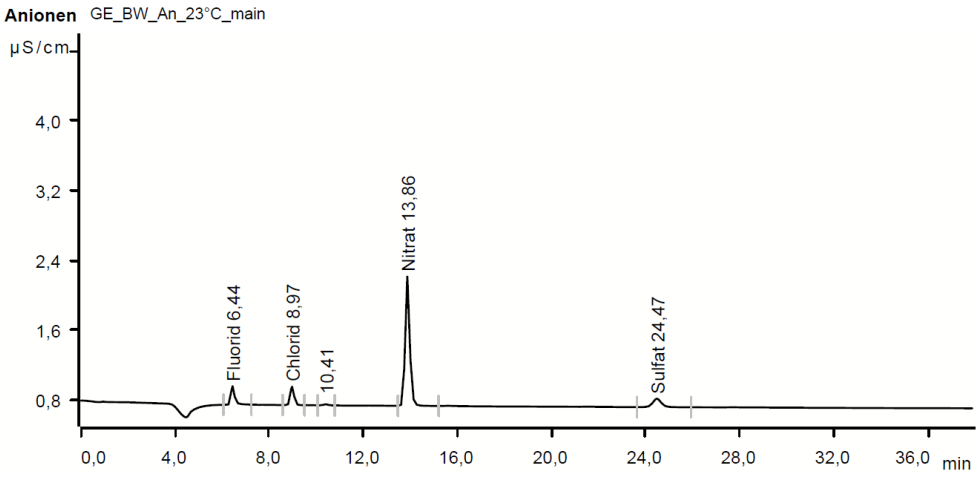


Figure 32 Chromatogram of the blank value at 23 °C

The measured values are below the quantification limit. No outgassing of inorganic acids could be quantified.

6.8.2.2 Measurement at 90 °C

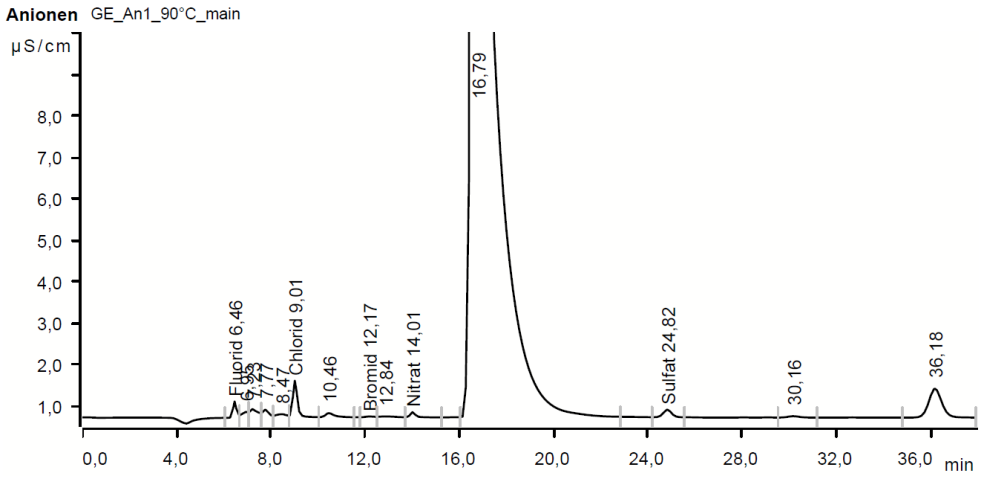


Figure 33 Chromatogram of the sample measurement at 90 °C

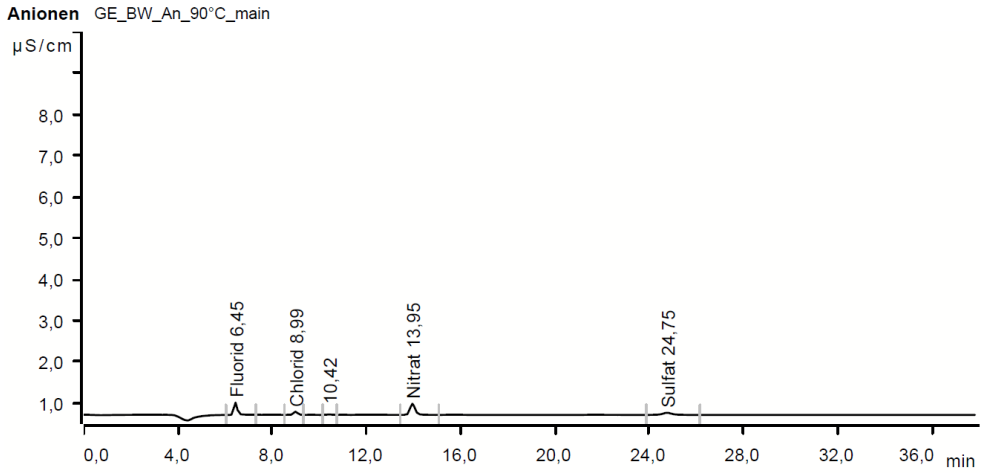


Figure 34 Chromatogram of the blank value at 90 °C

The measured values are below the quantification limit. No outgassing of inorganic acids could be detected.

6.8.3 Material classification

Contaminant Category (x)	SER_a [1] 23 °C [g/m²s]	SER_a [1] 90 °C [g/m²s]	ISO-ACC_m Class(x) based on 23 °C
NH_3	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**
HF	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**
HCl	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**
HBr	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**
HNO_3	< 2,9 x 10^{-9}	< 2,9 x 10^{-9}	**<-8.5**
H_3PO_4	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**
H_2SO_4	< 2.9 x 10^{-9}	< 2.9 x 10^{-9}	**<-8.5**

Figure 35 Classification results in accordance with VDI 2083 Sheet 17. [1] SER_a: area-specific emission rate

6.9 Results (VOC/SVOC)

6.9.1 Measurement at 23 °C

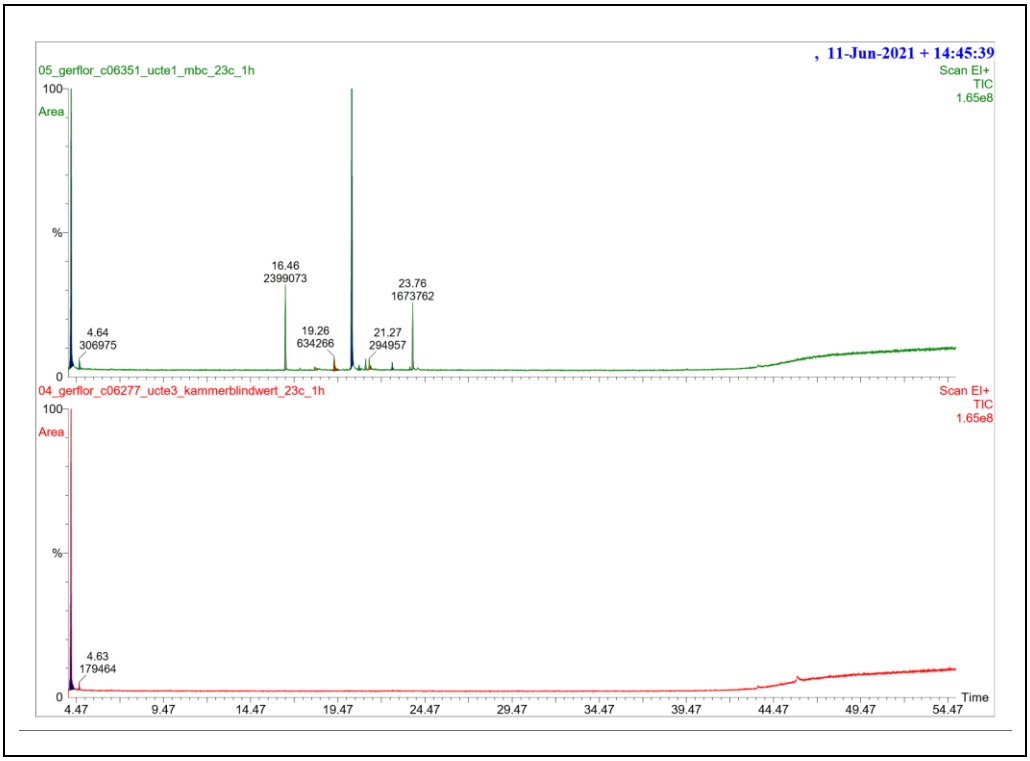


Figure 36 Outgassing test: chromatograms of blank value and sample measurement at 23 °C

The table below lists emission values in relation to surface area, volume and mass of detected VOC and SVOC substances at 23 °C and a normed outgassing time of 1 s. The blank value of the system (if known) is subtracted.

Substance	RT	Surface area	Volume	Mass
Mipolam Biocontrol Clean	in min	in g/m²s	in g/m³s	in g/g*s
CH-Compound	16.46	47	1.0E-08	5.2E-05
CH-/CHO-Compound	18.14	4	9.1E-10	4.5E-06
CH-Compound	19.26	12	2.7E-09	1.4E-05
CH-/CHO-Compound	20.27	351	7.8E-08	3.9E-04
CH-/CHO-Compound	20.68	4	9.6E-10	4.8E-06
CH-/CHO-Compound	21.07	6	1.3E-09	6.6E-06
CH-Compound	21.27	6	1.3E-09	6.4E-06
CH-Compound	21.36	2	5.1E-10	2.5E-06
CH-Compound	22.59	4	9.2E-10	4.6E-06
CH-Compound	23.60	2	3.9E-10	2.0E-06

Figure 37 Results of the VOC and SVOC outgassing test at 23 °C

Contaminant categories relevant to cleanrooms are highlighted in color in the table above: Amine: blue; Organophosphates: orange; Siloxanes: yellow; Phthalates: green.

6.9.2 Measurement at 90 °C

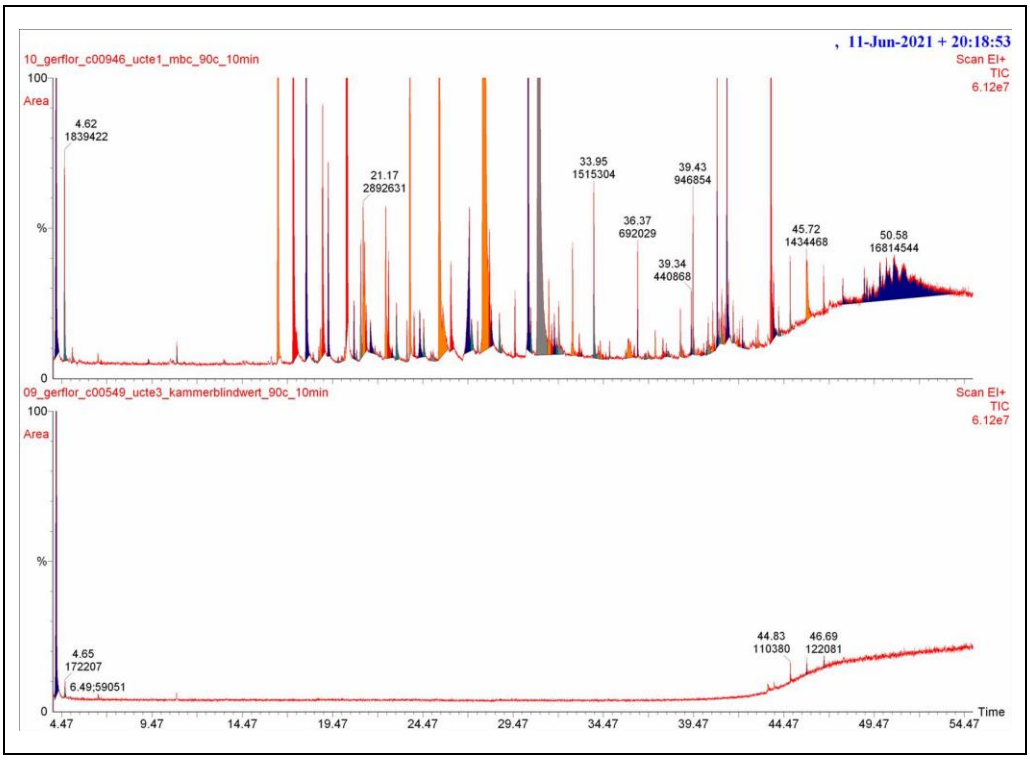


Figure 38 Outgassing test: chromatograms of blank value and sample measurement at 90 °C

The table below lists emission values in relation to surface area, volume, and mass of detected VOC and SVOC substances at 90 °C and a normed outgassing time of 1 s. The blank value of the system (if known) is subtracted.

Substance	RT	Surface area	Volume	Mass
Mipolam Biocontrol Clean	in min	in g/m²s	in g/m³s	in g/g*s
CH-/CHO-Compound	6.48	1	1.5E-09	7.7E-06
CH-/CHO-Compound	6.63	1	1.4E-09	7.0E-06
CH-/CHO-Compound	9.28	1	1.2E-09	5.9E-06
D3 Siloxane	10.85	3	3.9E-09	1.9E-05
N,N'-Bis(Carbobenzyloxy)-lysine methyl(ester)	13.46	2	1.7E-09	8.6E-06
CH-/CHO-Compound	16.45	203	2.2E-07	1.1E-03
CH-/CHO-Compound	17.29	208	2.3E-07	1.1E-03
Benzaldehyde	18.01	136	1.5E-07	7.5E-04
CH-/CHO-Compound	18.40	2	2.4E-09	1.2E-05
CH-/CHO-Compound	18.71	3	3.4E-09	1.7E-05
CH-/CHO-Compound	18.80	8	8.6E-09	4.3E-05

CH-/CHO-Compound	18.92	59	6.6E-08	3.3E-04
CH-Compound	19.23	40	4.4E-08	2.2E-04
CH-/CHO-Compound	19.81	2	1.8E-09	9.2E-06
CH-/CHO-Compound	19.95	2	2.3E-09	1.2E-05
CH-/CHO-Compound	20.15	3	3.0E-09	1.5E-05
CH-/CHO-Compound	20.27	1079	1.2E-06	6.0E-03
CH-/CHO-Compound	20.66	12	1.3E-08	6.6E-05
CH-/CHO-Compound	20.81	2	2.7E-09	1.4E-05
CH-/CHO-Compound	21.04	26	2.9E-08	1.5E-04
CH-/CHO-Compound	21.17	57	6.3E-08	3.1E-04
CH-Compound	21.34	10	1.1E-08	5.4E-05
Benzyl Alcohol	21.57	12	1.3E-08	6.6E-05
CH-/CHO-Compound	21.81	2	1.8E-09	9.0E-06
CH-/CHO-Compound	22.10	1	1.6E-09	8.2E-06
CH-/CHO-Compound	22.41	37	4.1E-08	2.1E-04
CH-Compound	22.56	27	2.9E-08	1.5E-04
CH-/CHO-Compound	22.77	3	3.4E-09	1.7E-05
CH-/CHO-Compound	23.01	16	1.7E-08	8.7E-05
CH-Compound	23.60	8	8.4E-09	4.2E-05
Cyclohexene, 1-methyl-4-(1-methylethylidene)-	23.76	120	1.3E-07	6.6E-04
CH-/CHO-Compound	23.99	9	9.6E-09	4.8E-05
CH-/CHO-Compound	24.30	15	1.7E-08	8.5E-05
CH-/CHO-Compound	24.52	9	1.0E-08	5.1E-05
CH-/CHO-Compound	25.04	7	7.4E-09	3.7E-05
N-Formylmorpholine	25.39	280	3.1E-07	1.5E-03
CH-/CHO-Compound	26.02	24	2.7E-08	1.3E-04
CH-/CHO-Compound	27.05	66	7.3E-08	3.6E-04
CH-/CHO-Compound	27.18	12	1.3E-08	6.7E-05
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	27.51	6	6.4E-09	3.2E-05
CH-/CHO-Compound	27.84	1503	1.7E-06	8.3E-03
CH-/CHO-Compound	28.17	25	2.8E-08	1.4E-04
CH-/CHO-Compound	28.26	11	1.3E-08	6.3E-05
CH-/CHO-Compound	28.71	10	1.1E-08	5.6E-05
CH-/CHO-Compound	28.86	1	1.5E-09	7.3E-06
CH-/CHO-Compound	28.86	1	1.5E-09	7.3E-06
CH-/CHO-Compound	29.37	1	1.4E-09	6.8E-06

CH-/CHO-Compound	29.57	11	1.2E-08	5.9E-05
CH-/CHO-Compound	30.31	222	2.4E-07	1.2E-03
CH-/CHO-Compound	30.45	9	1.0E-08	5.2E-05
Ethanol, 1-methoxy-, benzoate	30.91	4017	4.4E-06	2.2E-02
CH-/CHO-Compound	31.44	20	2.2E-08	1.1E-04
CH-/CHO-Compound	31.61	8	8.8E-09	4.4E-05
CH-/CHO-Compound	31.75	11	1.2E-08	5.9E-05
CH-/CHO-Compound	31.88	4	4.7E-09	2.3E-05
CH-/CHO-Compound	32.00	17	1.9E-08	9.5E-05
CH-/CHO-Compound	32.77	22	2.4E-08	1.2E-04
CH-/CHO-Compound	33.13	6	6.6E-09	3.3E-05
CH-/CHO-Compound	33.26	2	1.7E-09	8.5E-06
CH-/CHO-Compound	33.95	30	3.3E-08	1.6E-04
CH-/CHO-Compound	34.19	5	5.2E-09	2.6E-05
CH-/CHO-Compound	34.30	5	5.0E-09	2.5E-05
CH-/CHO-Compound	34.46	1	1.3E-09	6.3E-06
CH-/CHO-Compound	34.60	1	1.2E-09	6.1E-06
CH-/CHO-Compound	34.82	3	2.9E-09	1.5E-05
CH-/CHO-Compound	35.71	2	1.9E-09	9.4E-06
CH-/CHO-Compound	35.85	14	1.5E-08	7.7E-05
CH-/CHO-Compound	36.19	3	3.2E-09	1.6E-05
Butylated Hydroxytoluene	36.37	14	1.5E-08	7.5E-05
CH-/CHO-Compound	36.83	2	2.7E-09	1.4E-05
CH-/CHO-Compound	36.94	3	3.3E-09	1.7E-05
CH-/CHO-Compound	37.35	4	4.5E-09	2.3E-05
CH-/CHO-Compound	37.76	6	6.2E-09	3.1E-05
CH-/CHO-Compound	37.95	2	1.9E-09	9.5E-06
CH-/CHO-Compound	38.05	3	2.9E-09	1.4E-05
CH-/CHO-Compound	38.73	7	8.2E-09	4.1E-05
CH-/CHO-Compound	38.82	3	3.1E-09	1.5E-05
CH-/CHO-Compound	38.93	1	1.3E-09	6.5E-06
CH-/CHO-Compound	39.34	9	9.6E-09	4.8E-05
CH-/CHO-Compound	39.43	19	2.1E-08	1.0E-04
CH-/CHO-Compound	39.50	2	2.3E-09	1.1E-05
CH-/CHO-Compound	39.74	2	2.5E-09	1.2E-05
CH-/CHO-Compound	39.92	2	2.3E-09	1.1E-05
CH-/CHO-Compound	40.02	2	1.8E-09	9.0E-06

CH-/CHO-Compound	40.19	2	2.5E-09	1.2E-05
CH-/CHO-Compound	40.28	10	1.1E-08	5.4E-05
CH-/CHO-Compound	40.53	9	1.0E-08	5.1E-05
CH-/CHO-Compound	40.63	2	2.7E-09	1.4E-05
CH-/CHO-Compound	40.77	43	4.7E-08	2.4E-04
CH-/CHO-Compound	40.87	5	5.8E-09	2.9E-05
CH-/CHO-Compound	41.03	12	1.4E-08	6.9E-05
CH-/CHO-Compound	41.11	7	7.3E-09	3.7E-05
CH-/CHO-Compound	41.22	6	6.5E-09	3.2E-05
CH-/CHO-Compound	41.31	110	1.2E-07	6.1E-04
CH-/CHO-Compound	41.65	5	6.0E-09	3.0E-05
CH-/CHO-Compound	41.73	1	1.6E-09	8.2E-06
CH-/CHO-Compound	41.87	3	3.0E-09	1.5E-05
CH-/CHO-Compound	42.00	4	4.0E-09	2.0E-05
CH-/CHO-Compound	42.17	5	5.1E-09	2.5E-05
CH-/CHO-Compound	42.26	2	2.3E-09	1.1E-05
CH-/CHO-Compound	42.92	2	2.2E-09	1.1E-05
CH-/CHO-Compound	43.03	4	4.7E-09	2.3E-05
CH-/CHO-Compound	43.74	167	1.9E-07	9.3E-04
CH-/CHO-Compound	43.90	15	1.6E-08	8.1E-05
CH-/CHO-Compound	44.18	6	6.6E-09	3.3E-05
CH-/CHO-Compound	44.82	10	1.1E-08	5.7E-05
CH-/CHO-Compound	45.72	28	3.1E-08	1.6E-04
CH-/CHO-Compound	46.68	7	8.1E-09	4.1E-05
CH-/CHO-Compound	50.58	330	3.6E-07	1.8E-03
CH-/CHO-Compound	43.90	15	1.6E-08	8.1E-05
CH-/CHO-Compound	44.18	6	6.6E-09	3.3E-05

Figure 39 Results of the VOC and SVOC outgassing test at 90 °C

Contaminant categories relevant to cleanrooms are highlighted in color in the table above: Amine: blue; Organophosphates: orange; Siloxanes: yellow; Phthalates: green.

6.9.3 Material classification

Contaminant Category (x)	SER_a [1] 23 °C [g/m²*s]	SER_a [1] 90 °C [g/m²*s]	ISO-ACC_m- Class (x) based on 23 °C
VOC	1.7×10^{-7}	9.4×10^{-6}	**-8.2**
SVOC	$< 2.8 \times 10^{-10}$	9.3×10^{-7}	**< -9.6**
Amines	$< 2.8 \times 10^{-10}$	$< 1.7 \times 10^{-9}$	--
Organophosphates	$< 2.8 \times 10^{-10}$	$< 1.7 \times 10^{-9}$	--
Siloxanes	$< 2.8 \times 10^{-10}$	3.9×10^{-9}	--
Phthalates	$< 2.8 \times 10^{-10}$	$< 1.7 \times 10^{-9}$	--

Figure 40 Classification results in accordance with VDI 2083 Sheet 17. [1] SER_a: area-specific emission rate

7 Riboflavin test in accordance with VDMA information sheet

To assess the cleanability of the test pieces, a fluorescent contaminant was applied on the surfaces. The contamination was subsequently removed using a reproducible cleaning process. After cleaning, the success of the cleaning procedure was evaluated based on the presence of any residual contamination. The use of a fluorescent pigment enabled areas to be clearly visualized which are difficult to clean (edges, angles, depressions, etc.). Cleanability was assessed qualitatively as it is not possible to obtain quantitative data.

The test was carried out in accordance with the VDMA information sheet "Riboflavin test for low germ or sterile process technologies".

7.1 Test conditions

A test solution composed of 0.2 g riboflavin, 1000 ml ultra-pure water and 1 g hydroxyethylcellulose was used as a contaminant in the test.
The test contaminant was sprayed onto the test piece using a pump dispenser.

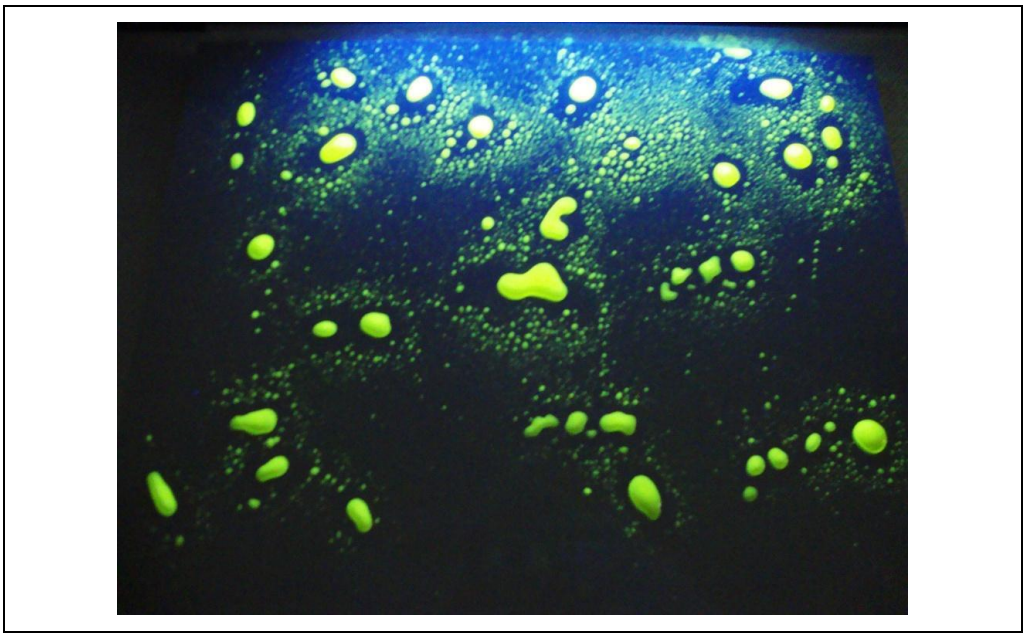


Figure 41 Test contamination adhering to the test piece illuminated by a handheld UV-lamp

The fluorescent contamination was visualized using a handheld UV-lamp with a wavelength of 366 nm and recorded with the aid of a digital camera.

7.2 Linear wiping simulator

To standardize the cleaning procedure a linear wiping simulator was used.
The linear wiping simulator is a linear axis which pushes an aluminum block with a defined weight of 1 kg and defined contact pressure of $1x10^{-3}$ N/mm^2 over the surface of the test piece.
At the aluminum block an immersed microfiber cloth can be fixed. The microfiber cloth will be pushed with a velocity of 1m/s over the surface. The block has the size of 12 cm x 8 cm.

Figure 42 Linear wiping simulator

7.3 Parameters

Test contamination:	0.2 g riboflavin, 1 g hydroxethylcellulose in 1000 ml ultra-pure water
Drying time:	2-3 h
Contact pressure:	1 x 10^{-3} N/mm^2
Velocity:	1 m/s
Cleaning cloth:	looped microfiber cloth 75% polyester, 25% polyamide
Wavelenght:	366 nm
Number of wiping cycles:	3
Number of repetitions:	3

7.4 Test procedure

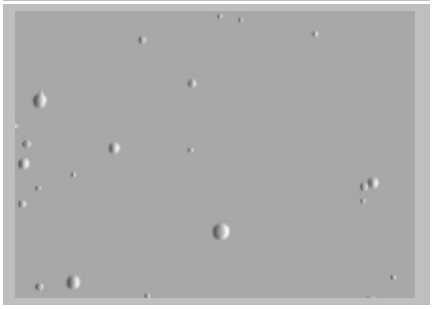
The contamination was cleaned after drying. This represents the expected worst case scenarios for flooring systems.

The test solution was sprayed uniformly onto the test surface and allowed to dry at room temperature for a period of two or three hours. A digital photo of the dried test surface was taken under UV-light. The surface was then cleaned in three cycles using the linear wiping simulator, whereby a microfiber cloth was immersed completely into ultra-pure water and then wrung out.

The microfiber cloth was then folded once, wrapped around the aluminum block of the linear wiping simulator and pushed over the test surface with a contact pressure of 1x10^{-3} N/mm^2 and at a velocity of 1 m/s. The cycle was repeated two more times. The residual contamination was then evaluated under the UV-lamp and documented by way of a digital photo.

7.5 Classification according to ISO 4628-1 and VDI 2083 Part 17

Rating of the cleaning efficacies of the test surfaces is done visually by assessment of the amount of fluorescent residues according to ISO 4628-1 and -2. According to VDI 2083 Part 17, the cleaning efficacy can be classified as follows:

Rating of cleaning efficacy according to ISO 4628-1	Visual assessment according to ISO 4628-1	Classification according to VDI 2083 Part 17	Reference pictures according to ISO 4628-2
0	No residues visible at all	excellent	
1	Very few, small, barely significant residues or number of residue spots	very good	
2	Few, small, but significant residues or number of residue spots	good	

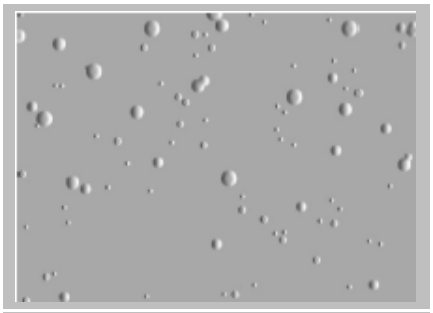
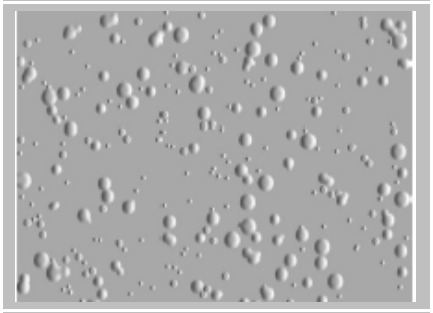
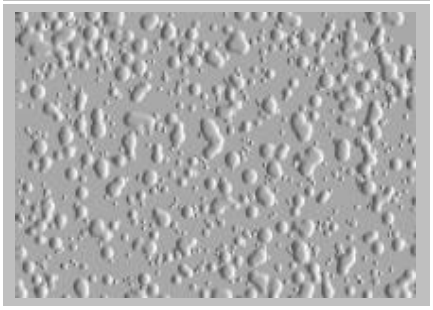
3	Moderate residues or number of residue spots	weak	
4	Considerable residues or number of residue spots	very weak	
5	Dense pattern of residues or residue spots	none	

Figure 43 Classification of the cleaning efficacies

7.6 Results

The contamination applied is fluorescent yellow in color and clearly visible. Other reflections on the pictures belong to the UV-lamp or other fluorescent particles for example dust particles. The results of the test are depending on the visual assessment. Sometimes it is not possible to discern the various reflections on the digital pictures therefor the visual assessment is the essential factor.

All surfaces are hydrophobic, making it impossible to apply a closed film of contamination. The hydrophobic surfaces made it much easier to remove the test contamination.

The cleaned area of the test surface has a width of about 12 cm.

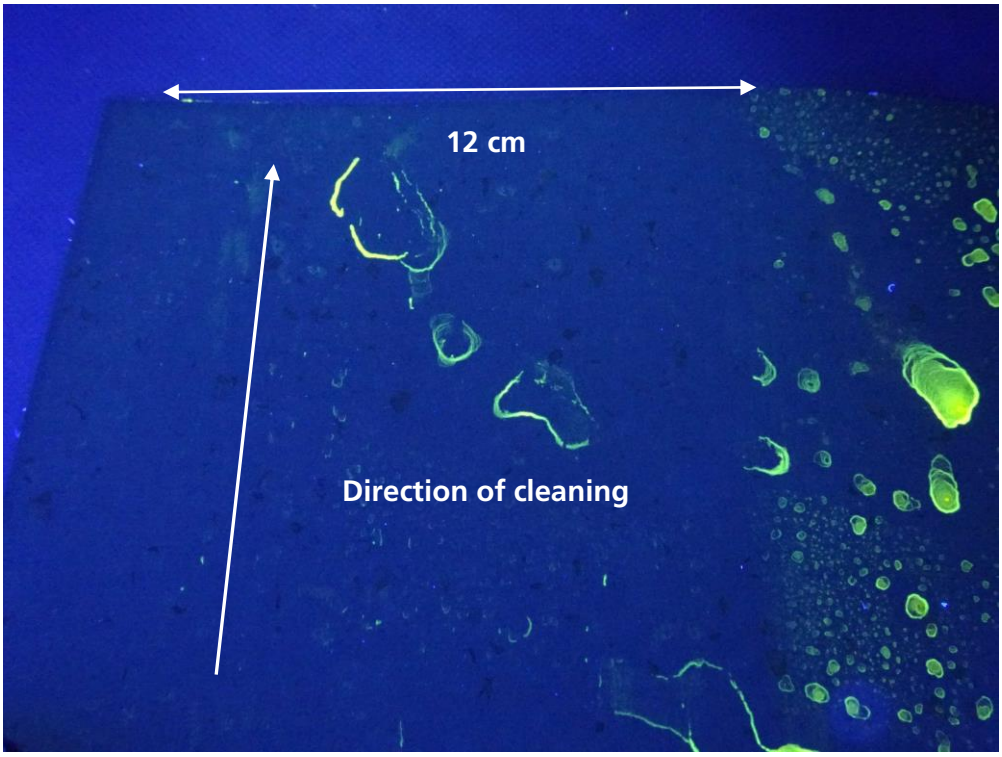


Figure 44 Cleaned area

7.7 Cleaning the previous dried contamination

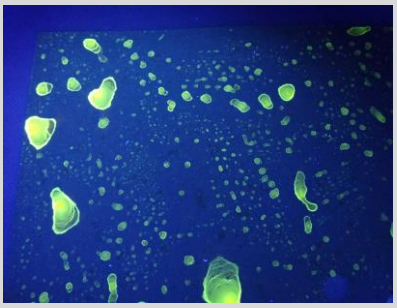
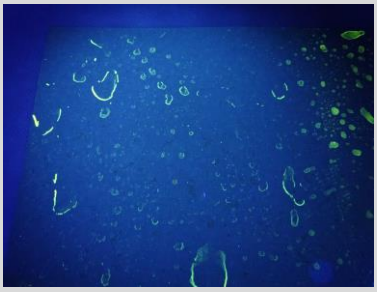
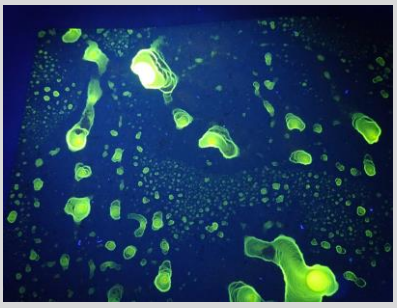
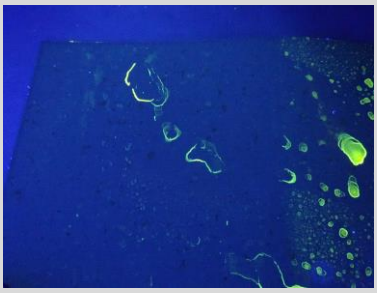
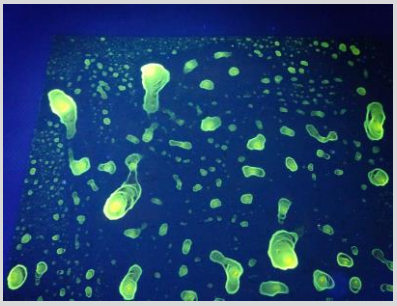
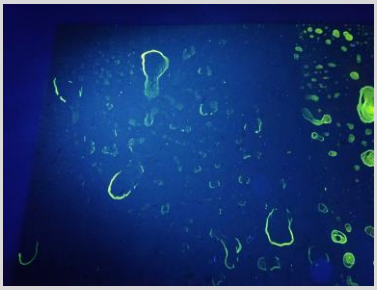
Digital pictures under UV-light	
Before cleaning	**After three cleaning-cycles**
	
Sample 1	3; weak
	
Sample 2	3; weak
	
Sample 3	3; weak
Result	**3; weak**

Figure 45 Results for Mipolam Biocontrol Clean

7.8 Summary

Test piece	Dried up
Mipolam Biocontrol Clean	**3; weak**

8 Chemical resistance

Chemical resistance tests show to what extent the materials under investigation may be used in a clean manufacturing environment. Among other things, the materials must be resistant to cleaning, process and disinfection reagents. The tests were carried out in accordance with the procedure laid down in ISO 2812-1 and chemical resistance to 10 typical reagents was tested.

8.1 Test procedure

In the chemical resistance tests, the material samples were subjected to a defined stress using the test chemicals. The determination was made using the immersion test procedure laid down in ISO 2812-1.

With the immersion test, a complete material sample is placed in a receptacle filled with the test chemical and then hermetically sealed.

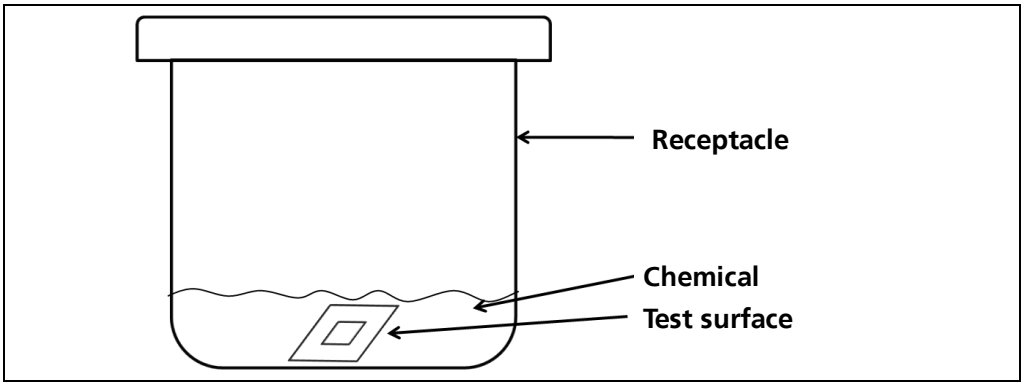


Figure 46 Diagrammatic sketch: immersion of a test sample into a chemical bath

Figure 47 Photo of a typical test set-up: test sample immersed in a chemical bath

The test samples were subjected to each reagent for a period of one, three, six and twenty-four hours and then examined for visible alterations.

Tests were carried out at room temperature in accordance with ISO 2812-1 ("Determination of resistance to liquids – Part 1: Immersion in liquids other than water").

On completion of the stress period, the test chemical was wiped off the test surface with a cleanroom cloth and inspected. The sample was reassessed after one hour to see if further alterations had taken place or if any alterations had lessened.

8.2 Assessment criteria

The test area was visually assessed in accordance with ISO 4628-1:2003 with regard to the following criteria:

- Type of damage (alteration in degree of shine, discoloration or yellowing, swelling, softening or altered resistance to scratching, any other noticeable alterations)
- Amount of damage (N-values)
- Size of damage (S-values)
- Intensity of alteration (I-values)

8.2.1 Assessment of the amount of damage

The amount of damage to the coating, occurring in the form of irregularities or localized flaws in the coating which are irregularly distributed or only in specific places, is assessed according to the following table.

Value	Amount of damage
N0	No recognizable damage
N1	Very little, i.e. small, just recognizable amounts of damage
N2	Little, but significant amounts of damage
N3	Average amount of damage
N4	Severe amounts of damage
N5	Extreme amounts of damage

Figure 48 Criteria for assessing the amount of damage

8.2.2 Assessment of the size of damage

The average size of damage – if it makes sense – is assessed according to the following table.

Value	Size of damage
S0	Not visible on 10x magnification
S1	Only visible on 10x magnification
S2	Just visible with the naked eye
S3	Clearly visible up to 0.5 mm
S4	Area 0.5-5 mm
S5	Larger than 5 mm

Figure 49 Criteria for assessing the size of damage

8.2.3 Assessment of the intensity of alteration

The intensity of regular alterations in the appearance of a coating such as changes in color, e.g. yellowing, is assessed according to the following table.

Value	Intensity of alteration
I0	Unchanged, no recognizable alteration
I1	Very slight, just recognizable alteration
I2	Slight, clearly recognizable alteration
I3	Average, clearly recognizable up to 0.5 mm
I4	Severe alteration
I5	Extreme alteration

Figure 50 Criteria for assessing the intensity of alteration

The analysis is made as follows:

"Blistering, N2-S2" or "Discoloring, I1"

Any other noticeable irregularities are also documented.

8.2.4 Reagents utilized

To simulate stress on the material samples due to cleaning-, process- and disinfection agents, the following standardized CSM-reagents were used:

- Formalin (37 %)
- Ammoniac (25 %)
- Hydrogen peroxide (30 %)
- Sulfuric acid (5 %)
- Phosphoric acid (30 %)
- Peracetic acid (15 %)
- Hydrochloric acid (5%)
- Isopropanol (100 %)
- Sodium hydroxide (5 %)
- Sodium hypochlorite (5 %)

8.2.5 Classification

The average of each worst value (N, S, I) after 24 hours incubation of all ten tested chemicals gives the classification value according to the following chart:

Reference number (obtained average)	Classification
0	excellent
1	very good
2	good
3	weak
4	very weak
5	none

Figure 51 Chemical resistance: Classification

8.3 Results of the chemical resistance test

A table has been selected to document the test results in order to show the chemical resistance of the test surfaces to the reagents. All images were recorded using a Zeiss stereo microscope, a color camera and annular/ring field illumination. Identical settings were used to record all images to enable a direct comparison to be made.

8.3.1 Formalin 37 %

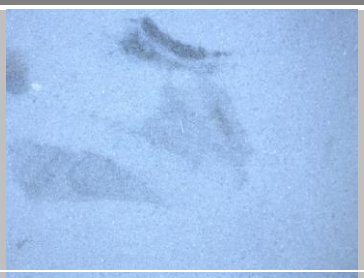
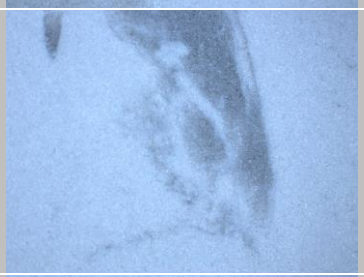
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 52 Floor covering Mipolam Biocontrol Clean subjected to formalin 37 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to formalin 37 % is excellent**.

8.3.2 Ammoniac 25 %

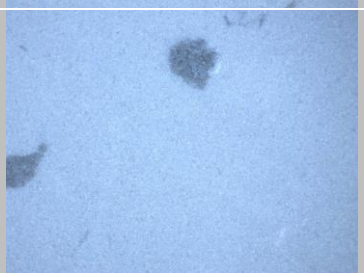
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 53 Floor covering Mipolam Biocontrol Clean subjected to ammoniac 25 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to ammoniac 25 % is excellent**.

8.3.3 Hydrogen peroxide 30 %

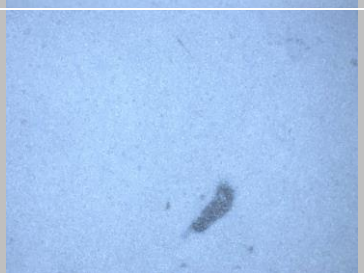
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 54 Floor covering Mipolam Biocontrol Clean subjected to hydrogen peroxide 30 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to hydrogen peroxide 30 % is excellent**.

8.3.4 Sulfuric acid 5 %

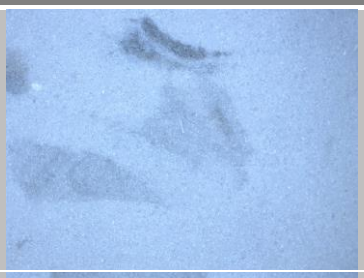
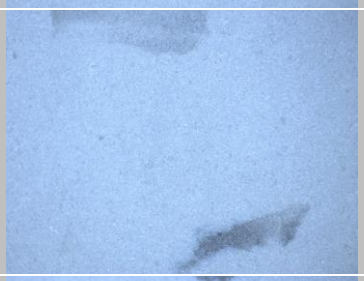
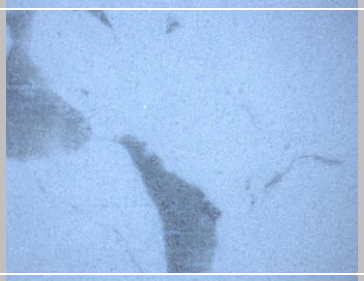
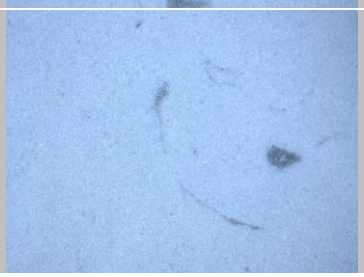
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 55 Floor covering Mipolam Biocontrol Clean subjected to sulfuric acid 5 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to sulfuric acid 5 % is excellent**.

8.3.5 Phosphoric acid 30 %

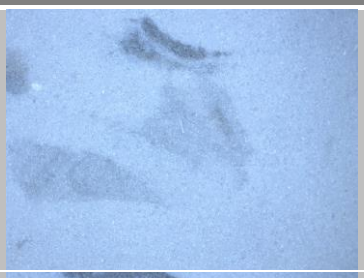
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 56 Floor covering Mipolam Biocontrol Clean subjected to phosphoric acid 30 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to phosphoric acid 30 % is excellent**.

8.3.6 Peracetic acid 15 %

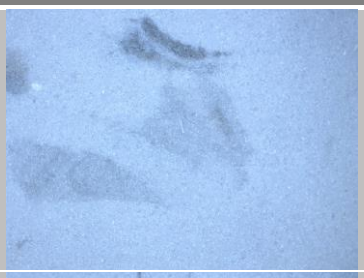
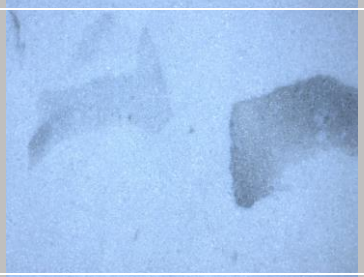
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**Deformation I1 Discoloring I1**

Figure 57 Floor covering Mipolam Biocontrol Clean subjected to peracetic acid 15 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to peracetic acid 15 % is very good**.

8.3.7 Hydrochloric acid 5 %

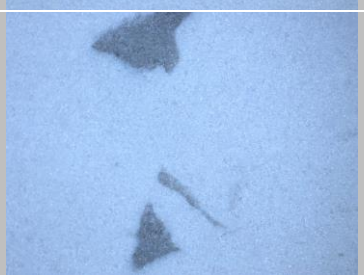
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 58 Floor covering Mipolam Biocontrol Clean subjected to hydrochloric acid 5 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to hydrochloric acid 5 % is excellent**.

8.3.8 Isopropanol 100 %

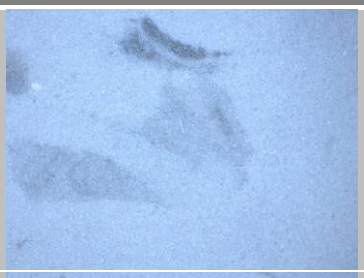
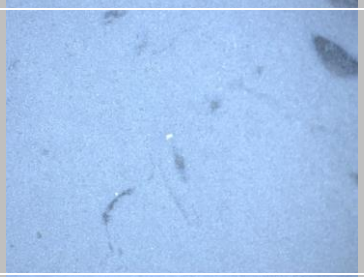
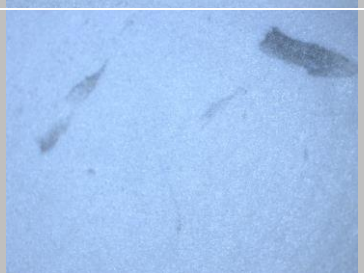
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		Deformation I1
6 h		Deformation I1
24 h		**Deformation I1**

Figure 59 Floor covering Mipolam Biocontrol Clean subjected to isopropanol 100 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to isopropanol 100 % is very good**.

8.3.9 Sodium hydroxide 5 %

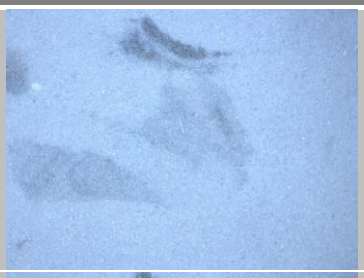
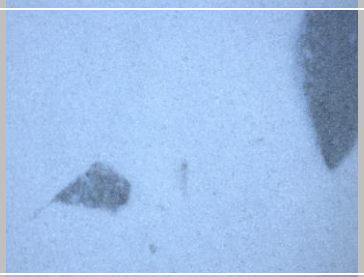
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 60 Floor covering Mipolam Biocontrol Clean subjected to sodium hydroxide 5 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to sodium hydroxide 5 % is excellent**.

8.3.10 Sodium hypochlorite 5 %

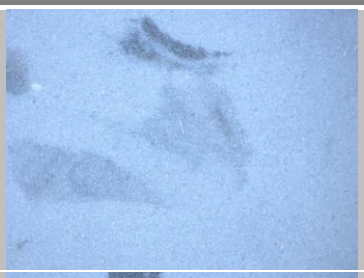
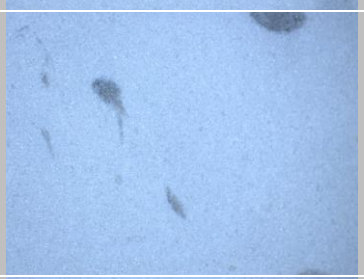
Time	Microscopic image 10x magnification	Value
Blank value		Before testing
1 h		N0
3 h		N0
6 h		N0
24 h		**N0**

Figure 61 Floor covering Mipolam Biocontrol Clean subjected to sodium hypochlorite 5 %

The test results show that the chemical resistance of the floor covering Mipolam Biocontrol Clean **to sodium hypochlorite 5 % is excellent**.

8.4 Summary results of the chemical resistance tests and CSM classification

The following tables give an overall assessment of the material sample Mipolam Biocontrol Clean:

Chemicals	Incubation			
	1 h	3 h	6 h	24 h
Formalin 37%	N0	N0	N0	**N0**
Ammoniac 25 %	N0	N0	N0	**N0**
Hydrogen peroxide 30%	N0	N0	N0	**N0**
Sulfuric acid 5 %	N0	N0	N0	**N0**
Phosphoric acid 30 %	N0	N0	N0	**N0**
Peracetic acid 15 %	N0	N0	N0	**I1**
Hydrochloric acid 5 %	N0	N0	N0	**N0**
Isopropanol 100 %	N0	I1	I1	**I1**
Sodium hydroxide 5 %	N0	N0	N0	**N0**
Sodium hypochlorite 5 %	N0	N0	N0	**N0**
Average value				**0,2**

Figure 62 Results of the chemical resistance tests on the material sample Mipolam Biocontrol Clean shown in the form of a table with corresponding values

Chemicals	Incubation			
	1 h	3 h	6 h	24 h
Formalin 37%	excellent	excellent	excellent	**excellent**
Ammoniac 25 %	excellent	excellent	excellent	**excellent**
Hydrogen peroxide 30%	excellent	excellent	excellent	**excellent**
Sulfuric acid 5 %	excellent	excellent	excellent	**excellent**
Phosphoric acid 30 %	excellent	excellent	excellent	**excellent**
Peracetic acid 15 %	excellent	excellent	excellent	**very good**
Hydrochloric acid 5 %	excellent	excellent	excellent	**excellent**
Isopropanol 100 %	excellent	very good	very good	**very good**
Sodium hydroxide 5 %	excellent	excellent	excellent	**excellent**
Sodium hypochlorite 5 %	excellent	excellent	excellent	**excellent**
CSM classification				**excellent**

Figure 63 Results of the chemical resistance tests on the material samples Mipolam Biocontrol Clean shown in the form of a table with the subsequent assessment into the CSM classification

9 Biological resistance

The aim of the tests is to assess the action of bacteria and fungi on the materials implemented.

According to GMP regulations, the materials utilized may not represent a contamination risk during later use in clean and hygienically sensitive productions. Special precautions are to be taken to reduce microbiological contamination risks to a minimum. In order to achieve this, among other things the materials utilized may not serve as a nutrient for microorganisms. Tests are carried out using the procedures laid down in the international standard ISO 846.

9.1 Test procedure

The test was performed in accordance with ISO 846 "Plastics – Evaluation of the action of microorganisms, Procedure A and C". The material samples were assessed visually.

The test serves to evaluate the behavior of materials with regard to the effects of specific fungi and bacteria. By carrying out the procedures A and C under the test conditions laid down in ISO 846, it can be assessed whether a material sample is either inert or interacts with fungi (Procedure A) and/or bacteria (Procedure C).

9.1.1 Procedure A (resistance to fungi)

Suspension of spores containing the following test strains:

- *Aspergillus niger* ASM 1957
- *Chaetomium globosum* ASM 1962
- *Paecilomyces variotii* ASM 1961
- *Penicillium pinophillum* ASM 1944
- *Trichoderma virens* ASM 1963

The test pieces are inoculated with the mixed spore suspension of the test fungi. In doing so, five parallel samples of each test piece are placed in separate Petri dishes. The Petri dishes are incubated in a receptacle containing a water reservoir to humidify the air.

Additionally, three stainless steel test pieces are inoculated and incubated as negative control samples.

Furthermore, two sterile samples are also prepared in parallel, onto which 3 ml of an ethanol-water mixture with a mass ratio of 70:30 is pipetted.

In accordance with ISO 846, the test samples are then incubated at 29 ± 1°C with a relative humidity of ≥ 95 % and visually inspected after the standardized test duration of 4 weeks.

9.1.2 Procedure C (resistance to bacteria)

Suspension of bacteria containing the following test strain:

- *Pseudomonas aeruginosa DSM 1253*

This bacterial suspension is mixed with a carbon-free* or low-carbon nutrient medium, liquefied and cooled to a temperature of 45°C.

The Petri dishes are filled with the inoculated agar. Once it has cooled, the test pieces are placed on the agar and the inoculated agar is then poured over them (layer approx. 1 mm thick covering the test piece) (5 parallel samples).

Additionally, three stainless steel test pieces are inoculated and incubated as negative control samples.

Furthermore, 2 sterile samples are also prepared in parallel, onto which 3 ml of an ethanol-water mixture with a mass ratio 70:30 is pipetted.

In accordance with ISO 846, the test samples are then incubated at 29 ± 1°C with a relative humidity of ≥ 95 % and visually inspected after the standardized test duration of 4 weeks.

9.2 Assessment

9.2.1 Procedure A (resistance to fungi)

Microbial growth on the test samples was assessed using the table shown in Figure 64.

Growth-intensity	Assessment
0	No growth visible under microscopic inspection
1a	No growth visible by eyesight, but with microscopic inspection. Up to 25% of the sample surface is covered.
1b	No growth visible by eyesight, but with microscopic inspection. Up to 50% of the sample surface is covered.
1c	No growth visible by eyesight, but with microscopic inspection. Over 50% of the sample surface is covered.
2	Growth visible by eyesight; up to 25% of the sample surface is covered
3	Growth visible by eyesight; up to 50% of the sample surface is covered
4	Strong growth visible by eyesight; over 50% of the sample surface is covered
5	Strong growth visible by eyesight; whole sample surface is covered

Figure 64 Evaluation of the biological resistance to fungi in accordance with ISO 846

The individual results from Figure 64 are interpreted and classified using the following table. The Classification is the worse value of test procedure A and C.

Reference number (obtained average)	Growth	Classification
0	no growth = resistant	**excellent**
1a, 1b, 1c	no growth visible by eyesight	**good**
2	visible by eyesight – up to 25%	**weak**
3	visible by eyesight – up to 50%	
4	visible by eyesight – over 50%	**none**
5	strong growth	

Figure 65 Biological resistance to fungi: Classification

9.2.2 Procedure C (resistance to bacteria)

Microbial growth on the test samples was assessed using the table shown in Figure 66.

Growth-intensity	Assessment
0	No growth visible under microscopic inspection
1	No growth visible by eyesight, but with microscopic inspection
2	Growth visible by eyesight
3	Strong growth visible by eyesight

Figure 66 Evaluation of the biological resistance to bacteria in accordance with ISO 846

The individual results from Figure 66 are interpreted and classified using the following table. The Classification is the worse value of test procedure A and C.

Reference number (obtained average)	Growth	Classification
0	no growth = resistant	**excellent**
1	no growth visible by eyesight	**good**
2	growth visible by eyesight	**weak**
3	strong growth	**none**

Figure 67 Biological resistance to bacteria: Classification

9.3 Results

9.3.1 Procedure A (resistance to fungi)

On completion of the tests, the results were assessed and interpreted as shown below:

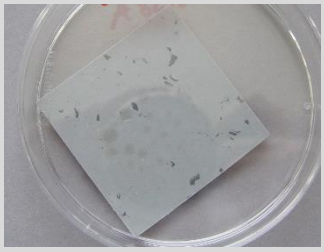
Assessment of intensity of fungi growth after 4 weeks incubation	
sample	Inoculated sample
	
(TP01) Mipolam Biocontrol Clean	**2; visible by eyesight – up to 25%**

Figure 68 Evaluation of biological resistance in accordance with ISO 846: Procedure A - Fungi

9.3.2 Procedure C (resistance to bacteria)

On completion of the tests, the results were assessed and interpreted as shown below:

Assessment of intensity of bacterial growth after 4 weeks incubation	
sample	Inoculated sample
	
(TP01) Mipolam Biocontrol Clean	**0; no growth = resistant**

Figure 69 Evaluation of biological resistance in accordance with ISO 846: Procdure C - Bacteria

9.4 Summary

The following table summarizes the results:

TP	Material	Fungi	Bacteria	Classification
01	Mip. Biocontrol Clean	2; weak	0; excellent	**weak**

Figure 70 Summary of evaluation of biological resistance in accordance with ISO 846

10 H_2O_2 absorption and desorption behavior

GMP controlled environments for sterile production require regular decontamination in order to minimize the biological burden to an accepted level. The usage of vaporized hydrogen peroxide (H_2O_2) to decontaminate controlled environments (e.g. isolators) is the preferred method due to several advantages to other decontamination procedures and decontaminating agents. Each H_2O_2 decontamination cycle ends with an aeration phase in order to reduce the H_2O_2 concentration to a specified limit. In addition to process-controlled parameters, e.g. rate of air-exchange, the aeration time is also influenced by the H_2O_2 absorption/desorption behavior of all exposed construction materials used in the controlled environment.

10.1 Experimental design

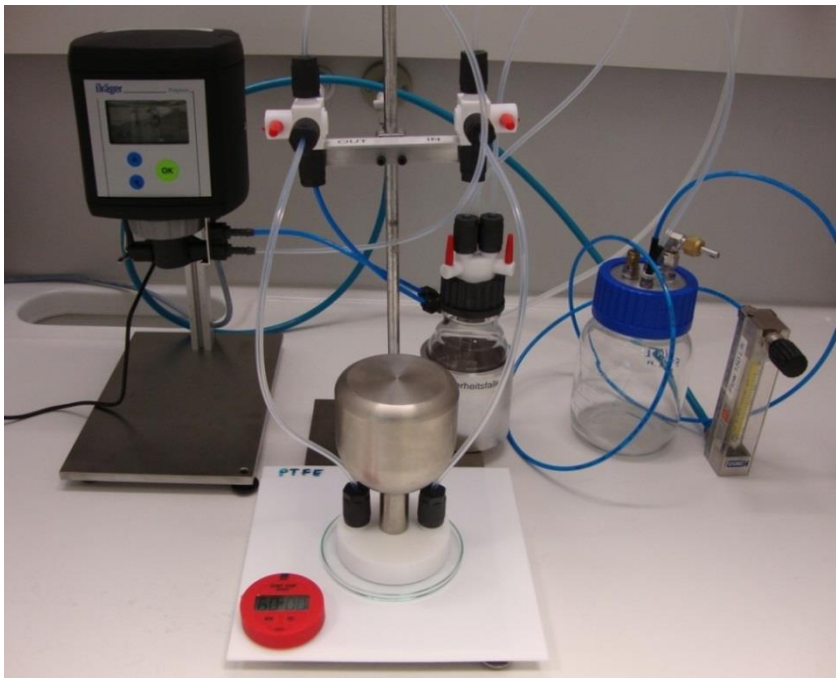


Figure 71 Experimental design. Left: H2O2 measurement device; center: exposure chamber, right: H2O2 source

A 1 l Schott laboratory glass bottle containing 200 ml of a 10 % hydrogen peroxide solution formes the H_2O_2 source. Ultra clean air is used as supply air with a volume flow of 150 l/h.

The following test parameters will be used according to VDI 2083 Part 20:

- Diameter: 65 mm
- Height: 5 mm
- Volume: 16.5 cm^3
- H_2O_2-exposed surface area: 33 cm^2
- H_2O_2 vapor concentration: 50 ± 20 ppm(V)
- Exposure duration: 60 min
- Purge flow rate: 150 l/h
- Measurement flow rate: 100 l/h
- Excess air flow rate: 50 l/h
- Air exchange rate (aeration): 100 min^{-1}

The exposure chamber is pressed onto the material sample supported by a weight. No hermetical seal encloses the gap between the exposure chamber and the sample allowing the excess air flow rate to escape. PFA tubing is used for all connections in contact with H_2O_2.

The H_2O_2 measurement device (Dräger Polytron 7000 with a corresponding low-concentration H_2O_2 sensor) is purged actively with 100 l/min during aeration.

10.2 Measurement strategy

The materials are exposed to H_2O_2 for 60 minutes. Subsequentely the chamber is flushed with ultra-pure air (aeration). Any H_2O_2 absorbed by the material desorbs from the material surface into the gas stream during the aeration step. The H_2O_2 concentration is measured online and illustrated in a graph with a logarithmic y-axis.

10.2.1 k-value

The k-value (in min) is the time required for the H_2O_2 concentration to reach 1/10 of the maximum concentration at the beginning of the aeration phase.

$$\mathbf{k = t\,(1/10\ c_{max}) - t\,(c_{max})}$$

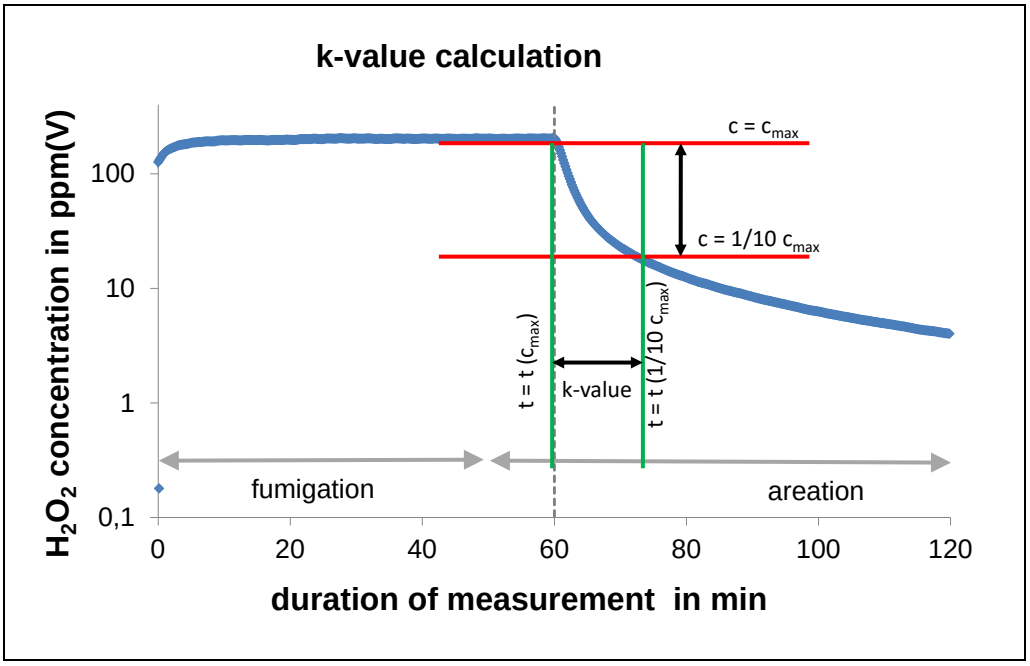


Figure 72 Calculation of the k-value

All samples are measured in triplicate in order to obtain three k-values and thus prove reproducibility. The average k-value of the blank measurement is subtracted from the individual k-values. The mean k-values correspond with the following classification:

K-value	H_2O_2 absorption and desorption kinetics: classification
≤ 5 min	non-absorptive
> 5 - ≤ 15 min	fast
> 15 - ≤ 60 min	medium
> 60 min	slow
Not determinable due to catalytic activity	catalytic

Figure 73 H_2O_2 absorption and desorption kinetics: classification

10.3 Results

10.3.1 Blank value

The blank value of the exposure chamber was measured two times:

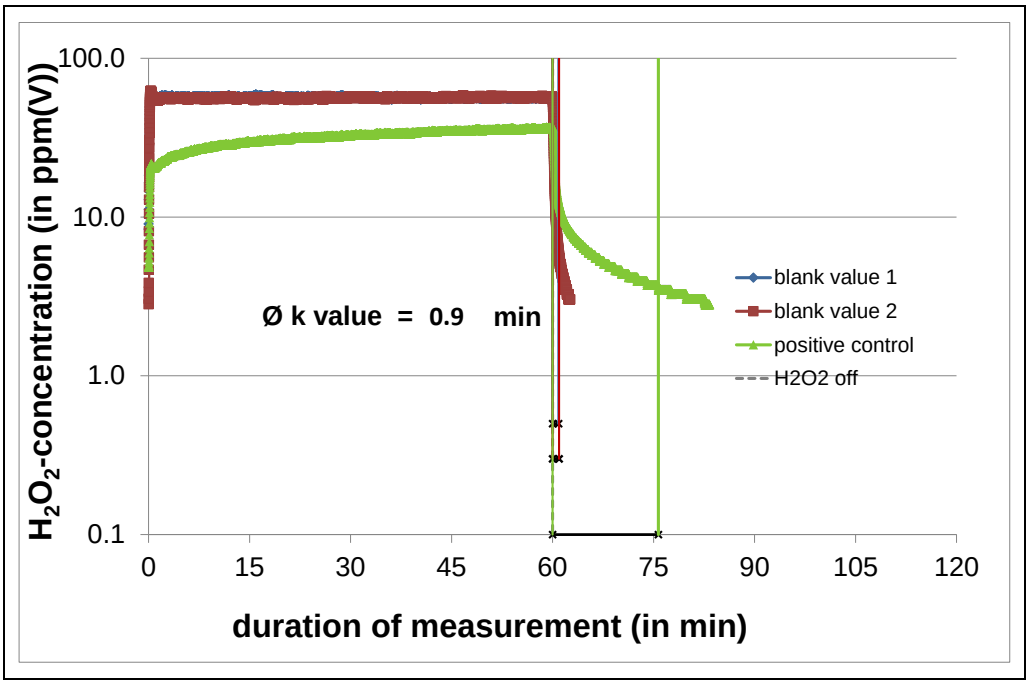


Figure 74 Blank value

10.3.2 Mipolam Biocontrol Clean

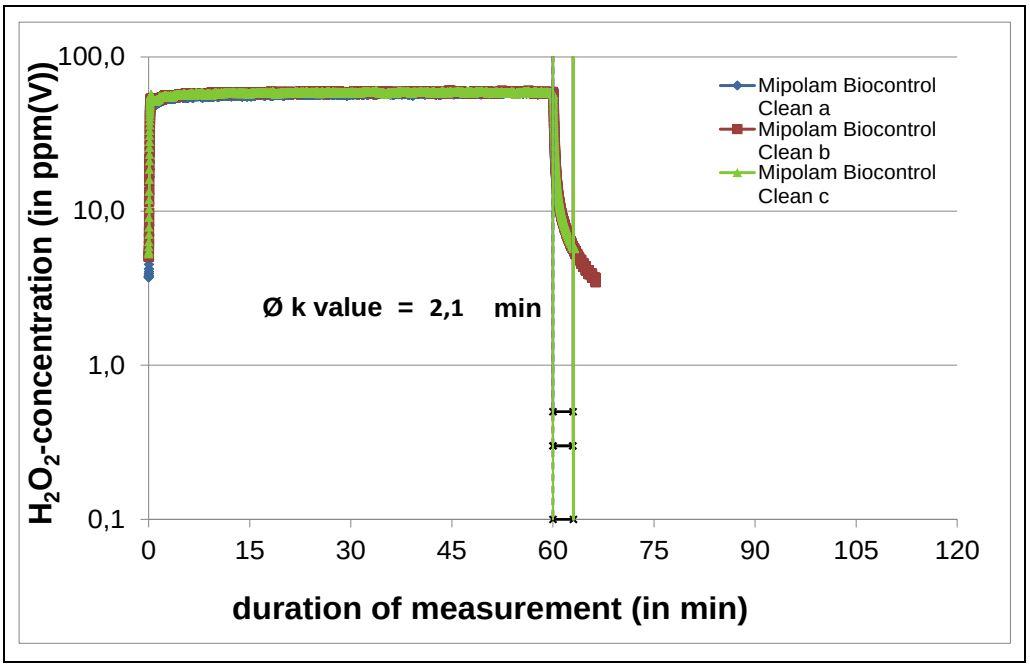


Figure 75 Absorption/Desorption: Mipolam Biocontrol Clean

10.4 K-values

For each measurement the materials were tested in triplicate. The following k-values, average k-values (Ø) and corresponding standard deviations (S.D.) were determined:

Test piece	Material	K-value [min]	Ø k-value [min]	S.D. [min]
TP01	Blank value Mipolam Biocontrol Clean	0.9	0.9 (blank value)	0
		0.9		
TP01	Mipolam Biocontrol Clean	2.1	2.1 (non-absorptive)	0
		2.1		
		2.2		

Figure 76 k-values of tested materials – numerical values