



colorex[®] EC

Cleanroom suitability certifications

HOMOGENEOUS VINYL TILE

forbo

FLOORING SYSTEMS

Content

Introduction	3
Impact of Colorex EC on a cleanroom environment	4
– Particle emission under frictional stress	4
– Airborne molecular contamination (AMC) / Outgassing	5
Resistance of Colorex EC	6
– Biological resistance - Action of microorganisms on Colorex EC	6
– Chemical resistance of Colorex EC for	7
Microbiological behaviour and particle decontamination ability of Colorex EC	8
– Assessment of the surface cleanability of Colorex EC	8
– Assessment of the microbiological behaviour - Adhesion of micro-organisms on Colorex EC	9
Appendix I “Cleanroom Suitable Materials” Qualification Certificate	11
Appendix II “Tested Device” Qualification Certificate	12
Technical specifications	13

colorex[®] EC

Introduction

The ISO standards for air cleanliness in cleanrooms as well as the current GMP regulations are imposing a strict contamination control to the pharmaceutical and to life science industries, they must present persistent results and compliance must be validated on a regular basis by trusted authorities.

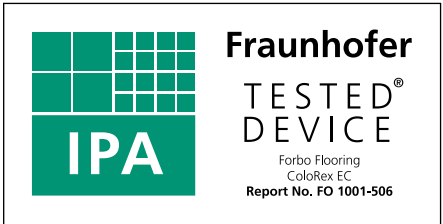
With Colorex EC, Forbo Flooring is delivering a floor covering product meeting all of these requirements and regulatory provisions. The cleanroom suitability of Colorex EC has been certified by the renowned Fraunhofer IPA Institute in Germany upon the completion of a comprehensive testing programme.

- The following tests were specifically carried out:
- Particle emission by dynamic friction and classification according to ISO 14644-1
 - Outgassing behaviour and classification according to ISO 14644-8
 - Adhesion of micro-organisms by Fraunhofer test method
 - Assessment of the microbial behaviour on surface according to ISO 846
 - Chemical resistance according to ISO 2812-1
 - Surface cleanability rating according to the German VDI guideline 2083, Part 9.1

The Fraunhofer Society in Germany is the largest organisation for applied research in Europe. It undertakes applied research of direct utility to private and public enterprises and of wide benefit to society.

The Fraunhofer Society includes 59 Institutes, each one specialised in a particular research field. The institutes are spread over different locations in Germany and employ 17’000 staff, the majority of which are qualified scientists and engineers.

Two thirds of the Society’s revenue is derived from contract research with private industries or from publicly financed research projects. Only one third is contributed by the government in the form of institutional funding.



Impact of Colorex EC on a cleanroom environment

The suitability of a product for use in a cleanroom or clean area is greatly influenced by its material composition. It is therefore necessary to know whether a building material can impact on a specific cleanroom environment and in the affirmative, to what extent.

The industrial alliance “Cleanroom Suitable Materials” (CSM) of the Fraunhofer IPA Institute has developed standardized procedures for determining the cleanroom suitability of materials. Depending on their area of application, their behaviour with regard to particle emission and outgassing is taken into consideration. The tests are carried out in a standardized way and 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 production environments and fields of application.

Particle emission under frictional stress

The ISO standard 14644-1 divides cleanrooms in classes by specifying for each class the highest admissible concentration of particles between 0.1 and 5.0 µm /m³ of cleanroom air.

It is therefore important to know and to limit the possible impact of a specific building material in this respect.

In this test, frictional stress has been simulated by a PA6 nylon wheel travelling over the Colorex EC specimen at a given speed and over a given distance. Three different load forces have been applied on the wheel, while each pass has been repeated three times.

Results of the particle emission test on application of tribological stress for Colorex EC:

Load level	Force applied by nylon wheel [N]	Detected number and size of released particles						ISO class in accordance with ISO 14644-8
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm	
B 06	150	2.2	2.6	2.9	3.0	3.1	3.5	4
B 09	225	1.0	1.0	1.0	1.0	1.0	1.0	
B 12	300	1.9	2.0	2.2	2.5	2.7	3.5	

Conclusion

The level of particulate contamination emitted during the application of tribological stress by a PA6 nylon wheel on Colorex EC lies within the permitted values of the corresponding Air Cleanliness Class ISO Class 4 in accordance with ISO 14644-1.

Airborne molecular contamination (AMC) / Outgassing

Products and processes that are sensitive to airborne contamination are found in many industries, such as aerospace, microelectronics, pharmaceuticals, medical devices, food and healthcare. Semiconductor manufacturing and aerospace are particularly sensitive to AMC, as it can cause corrosion, product degradation and significant yield losses. The ISO standard 14644-8 specifies the classification of AMC in cleanrooms and associated controlled environments in terms of airborne concentration of specific chemical substances (or group or category of substances) in the cleanroom air.

Testing was carried out in compliance with the established procedure developed by the CSM industrial alliance. The method of analysis used is referred to as “Thermo-Desorption / Gas Chromatography / Mass Spectrometry” (TD/GC/MS). This method allows for a qualitative and quantitative analysis and is suitable for testing material samples for the emission of Volatile Organic Compounds (VOC).

Outgassing was measured at 23°C and 90°C on samples prepared 120 days before.

Results of the outgassing tests of Colorex EC under thermal stress

Parameters				Outgassing quantity		
Sample area	Testing time	Temperature	Substance group tested	Detected	Standardised for 1 m² and 1 s	Classification in accordance with ISO 14644-8
m²	s	°C		g	g/m²s	ISO-AMC
0.001	3600	23	TVOC	3.0E-09	8.3E-10	-9.1
0.001	60	90	TVOC	5.6E-08	1.6E-08	

Conclusion

At a temperature of 23° C and an assumed sample surface area of 1 m², Colorex EC emitted a quantity of TVOC over a period of 1 s which did not exceed the stated limiting value for Class -9.1 according to ISO 14644-8 in a reference volume of 1 m³.

Remarks about contaminant groups relevant to cleanrooms:

No outgassing of the following groups of substances could be ascertained at 23° and at 90° C:

- Amines
- Organophosphates
- Siloxanes
- Phtalates
- SVOC

Note: the ISO standard 14644-8 currently considers only concentrations of AMC between 1 and 10⁻¹² g/m³ under cleanroom operational conditions. ISO-AMC classes are ranging from class 0 (highest concentration) to -12 (lowest concentration of contaminants). It is not the intention of this norm to describe the nature of airborne molecular contaminants and it does not give a classification of surface molecular contamination.

Resistance of Colorex EC

Floors in life science and pharmaceutical production environments are exposed to a number of stresses, including spillage of chemicals, repeated cleaning and disinfecting cycles with strong products, bio-decontamination procedures and the action of micro-organisms.

It is therefore important to know and to assess the behaviour of Colorex EC in these situations.

Biological resistance - Action of micro-organisms on Colorex EC

The aim of this test is to assess the action of bacteria and moulds on Colorex EC. According to the cGMP (current Good Manufacturing Practices) regulations, special precautions are to be taken to reduce microbiological contamination risks to a minimum. One of the precautions states that the materials used, the floor covering in our case, may not serve as a nutrient for micro-organisms.

Tests to assess this were carried out using the procedures laid down in the international standard ISO 846 "Plastics - Evaluation of the action of micro-organisms, Procedure A (moulds) and C (bacteria)".

Samples of Colorex EC were placed on a carbon-free mineral salt medium and inoculated with suspensions containing:

Moulds

- Aspergillus niger
- Penicillium funiculosum
- Paecilomyces variotii
- Gliocladium virens
- Chaetomium globosum

Bacteria

- Pseudomonas aeruginosa

Test samples were incubated at 24 °C with a relative humidity of 95 % and visually inspected after a standardized test duration of 4 weeks.

Growth intensity	Assessment
0	The material is not a nutrient for micro-organisms, it is inert or fungistatic. No growth visible under microscopic inspection.
1	The material contains nutrients that allow for a weak growth of micro-organisms. Growth visible under microscopic inspection, not visible by eyesight.
2 - 5	The material is being damaged by micro-organisms and contains nutrients that favour their growth. Growth or strong growth visible by eyesight.

Growth intensity of both moulds and bacteria on Colorex EC was 0.

Chemical resistance of Colorex EC

Resistance was tested against 14 typical chemicals, representative for the chemical substance categories present today in most cleaning products, disinfecting products and bio-decontamination procedures. In addition, resistance against a product representative for extremely alkaline cleaning and disinfecting solutions was tested ("Sodosil RA 08", pH 12 at 0.3% caustic cleaning solution).

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").

Chemical	Exposure 1 hour	Exposure 3 hours	Exposure 24 hours
Ethanol (100%)	resistant	resistant	resistant
Acetone (100%)	not resistant	not resistant	not resistant
Benzine	resistant	resistant	resistant
Isopropanol (70%)	resistant	resistant	resistant
Ultrapure water	resistant	resistant	resistant
Formalin (37%)	resistant	resistant	resistant
Ammoniac (25%)	resistant	resistant	resistant
Hydrogen peroxide (30%)	resistant	resistant	resistant
Sulphuric acid (5%)	resistant	resistant	resistant
Hydrochloric acid (5%)	resistant	resistant	resistant
Peracetic acid (1%)	resistant	resistant	resistant
Sodium hydroxide (20%)	resistant	resistant	partially resistant
Sodosil RA 08	resistant	resistant	resistant
Butyl acetate (100%)	not resistant	not resistant	not resistant
Diethyl ether (100%)	not resistant	not resistant	not resistant

Resistance data to other chemicals are available or can be arranged upon request.

Microbiological behaviour and particle decontamination ability of Colorex EC

For cleanroom applications that are particularly sensitive to contamination of surfaces by particles and/or micro-organisms, it will be important to know to what extent the material used for the floor can be kept free of particles and/or micro-organisms by standard surface cleaning procedures.

Assessment of the surface cleanability of Colorex EC

The ISO 14644-9 (Classification of surface cleanliness by particle concentration) and the German VDI 2083 Part 9.1 are specifying the cleanliness classes of hard surfaces in cleanrooms, such as walls, floors, equipment and any other sensitive surface. Classification is based on the max. permitted number and size of particles per given surface area.

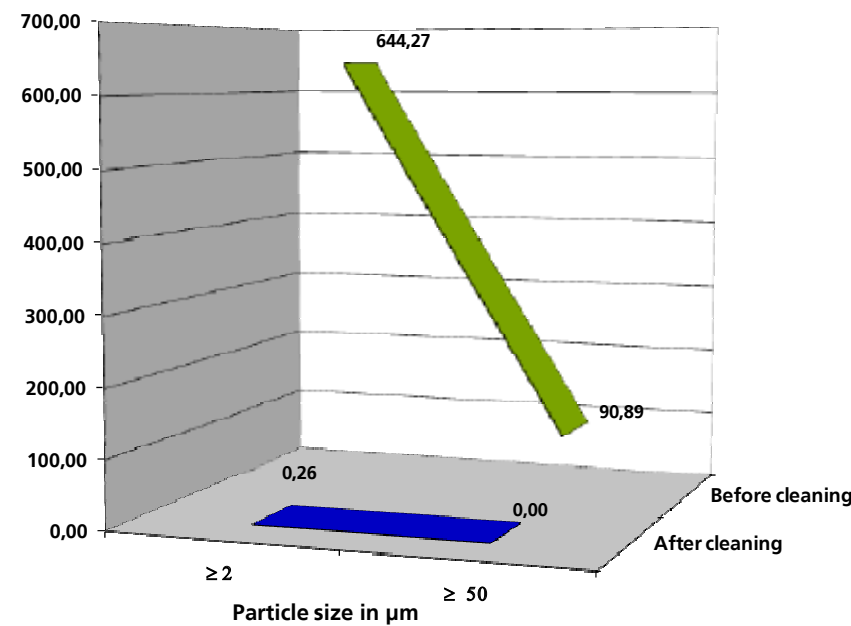
For this test, a Colorex EC tile was contaminated at 12 different points with various particles ranging from 1 to 100 µm. Particle detection and counting before (initial blank value) and after the contamination were carried out by a proprietary method of Fraunhofer IPA.

After cleaning the contaminated tile surface with a cleaning product and procedure representative for standard cleanroom use², the test surface was inspected again and the results were evaluated according to VDI 2083 Part 9.1.

Result and conclusion 1

The test result showed that a cleaning success of 99,98% could be attained by using the standard surface cleaning procedure. The initial blank value measurement of particles below 50 µm could be nearly re-established.

The following graph shows the particle size and count of the test area before and after cleaning with the above mentioned product and procedure:



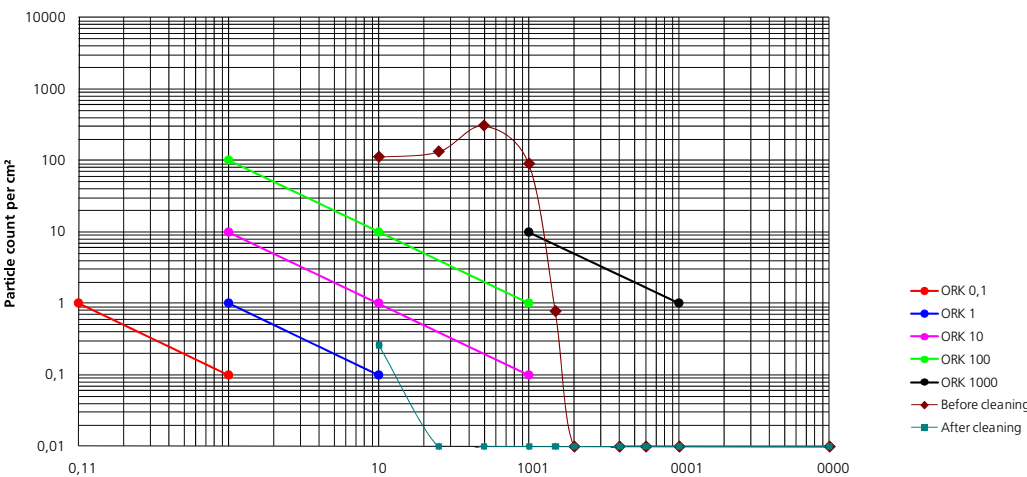
¹ 1 µm = 0,001 mm. The diameter of an average human hair is approx. 70 µm

² Cellulose-polyester cloth moistened with 5% Elma Clean 100 made up with deionised water

Result and conclusion 2

The German standard VDI 2083 Part 9.1 specifies five Surface Cleanliness Classes (SCC) ranging from class 0.1 to class 1000, depending upon the max. permitted particle size and particle count per cm².

The cleaning success correlated to this standard places Colorex EC between Surface Cleanliness Class 1 and 10.



Representation of the relative success of cleaning the test area correlated to Surface Cleanliness Classes in accordance with VDI 2083 Part 9.1

Assessment of the microbiological behaviour - Adhesion of micro-organisms on Colorex EC

The ISO 14698-1 (General principles and methods of biocontamination control) and the cGMP (current Good Manufacturing Practices) are stipulating that biological contamination must be kept under strict control.

To this purpose it will be very important to know to what extent a cleanroom surface can be decontaminated from potentially harmful micro-organisms.

For this test, Colorex EC samples were inoculated with suspensions of micro-organisms at various concentrations and incubated for 72 hours at 30° C and high relative humidity. After incubation, the sample areas were cleaned with ultrapure water. The amount of micro-organisms that were still adhering to the test surface after cleaning were taken as key indicator to assess the ability of Colorex EC to reduce surface micro-organism counts.

Five different cultures of micro-organisms were utilized:

- Escherichia coli (E. coli)
- Aspergillus niger (A. niger)
- Lactobacillus plantarum (L. plantarum)
- Staphylococcus saprophyticus (Staphylococcus sp.)
- Sacharomyces cerevisiae (S. cerevisiae)

Results and conclusions

The CFU counts (Colony Forming Units) per given surface area before and after cleaning were compared and evaluated regarding **suitability for use in pharmaceutical grade A and B zones according to the EC-GMP Annex 1.**

The comparison between CFU counts before and after cleaning generates a value called R-value. In the test evaluation, this R-value is used to calculate the achievable CFU reduction by cleaning, starting from a theoretical CFU load.

Clean areas for manufacturing sterile products are categorized into various classes according to the required cleanliness of the air and of surfaces. The following table lists the requirements of surface qualities as laid down in the EC-GMP.

Recommended limiting values for the microbial contamination of surfaces:

Cleanliness Class in accordance with EC-GMP	Max. permitted CFU count / contact plate (Ø 55mm)
A	<1
B	5
C	25
D	50

CFU reduction by cleaning with ultrapure water and achievable cleanliness class on Colorex EC:

Micro-organism	Theoretical CFU start	R-value	Achievable CFU end	Achievable cleanliness class in acc. with EC-GMP
E. coli	1000	2.4	4	B
A. niger	1000	3.2	1	B
L. plantarum	1000	3.4	0	A
Stahylococcus sp.	1000	4.6	0	A
S. cerevisae	1000	2.7	2	B



Forbo Flooring
Report No. FO 1001-506

Cleanroom[®] Suitable Materials

ColoRex EC
Particle (vs. PA6): ISO 4
TVOC (23°C/90°C): ISO -9.1/tested

Flooring & Coating

Qualification Certificate

We hereby certify that the material stated below which was provided by

Forbo Giubiasco SA

Via Industrie 16
6512 Giubiasco
Switzerland

has been awarded a Fraunhofer IPA CSM Certificate of Qualification with the report number FO 1001-506.


The tests performed in accordance with CSM procedures included particle emission during the application of frictional stress and outgassing at various temperatures. The tested material obtained following classification in accordance with the standard(s) listed below.

Material (Mat.)	ColoRex EC Everest*	
Particle	Reel-on-disc test; Normal force 300N Mat. vs. PA6	ISO Class 4 (see ISO 14644-1)
Outgassing at 23 °C / 73 °F	TVOC	ISO-AMC Class -9.1 (see ISO 14644-8)
Outgassing at 90 °C / 194 °F	Amines Organo-phosphates Siloxanes Phthalates	0.0 x 10 ⁻⁹ g/m ² s 0.0 x 10 ⁻⁹ g/m ² s 0.0 x 10 ⁻⁹ g/m ² s 0.0 x 10 ⁻⁹ g/m ² s

* The tested material was ColoRex EC Everest. According to the manufacturer's specifications, there is no influence on the test results by the differing colors.

Detailed information and the parameters of the test environment can be obtained from the Fraunhofer IPA CSM Test Report. The validity of this certificate is indefinite. For more information, visit our website at www.ipa-csm.com.

Stuttgart, March 4, 2010

i. A. 
Project manager



Fraunhofer

TESTED[®]
DEVICE

Forbo Flooring
ColoRex EC
Report No. FO 1001-506

Technical specifications

Colorex SD/EC meets the requirements of EN 649

Colorex EC		
	Total thickness	EN 428
	Collection size	15
	Commercial very heavy	EN 685
	Industrial general	EN 685
	Tile size	EN 427
		610 x 610 mm
		615 x 615 mm*
		613 x 1226 mm*
	Electrical resistance	EN 1081 (R1; R2)
		IEC 61340-4-1
		ANSI/ESD S7.1
		5 x 10 ⁴ ≤ R ≤ 10 ⁶ Ω
	Body voltage generation, with appropriate ESD shoes	IEC 61340-4-5
		ESD STM97.2
		< 30 V
	Slip resistance	DIN 51130
	Total weight	EN 430
	Dimensional stability	EN 434
	Residual indentation	EN 433
	Abrasion resistance	EN 660-1
	Castor chair	EN 425
	Light fastness	EN 20 105-B02
	Resistance to chemicals	EN 423
	Thermal conductivity	EN 12524
* upon request		

Colorex SD/EC meets the requirements of EN 14041

	Reaction to fire	EN 13501-1
	Slip resistance	EN 13893
	Static electrical propensity	EN 1815
	Electrical resistance	EN 1081

CSM and Tested Device classification

Particle emission	ISO 14644-1	Class 4
Outgassing at 23° C	ISO 14644-8	Class -9.1
Biological resistance	ISO 846	Growth intensity = 0
Chemical resistance	ISO 2812-1	see page 7 for results
Surface cleanability	VDI 2083 part 9.	SCC 1 – 10
Adhesion of microorganisms	EC-GMP Annex 1	A / B

Qualification Certificate

This is to certify that the product mentioned below provided by the company

Forbo Giubiasco SA

Via Industrie 16
6512 Giubiasco
Switzerland

has been awarded a Fraunhofer certificate TESTED DEVICE bearing the report number FO 1001-506.

The ColoRex EC Everest* has performed following tests:

- 1)The surface cleanability regarding particles is very well.
- 2)The chemical resistance after incubation (1, 3, 6 and 24 hours) could be proven to the following test reagents: Sodosil RA 08, Ethanol (100 %), Benzine, Isopropanol (70 %), Ultrapure water, Formalin (37 %), Ammoniac (25 %), Hydrogen peroxide (30 %), Sulfuric acid (5 %), Hydrochloric acid (5 %), Peracetic acid (1 %).
- 3)The surface cleanability regarding selected microorganisms shows useability for sterile room (Cleanliness Class A/B) in accordance with EC-GMP Annex 1.
- 4)The material is resistant against the action of microorganisms.

* The tested material was ColoRex EC Everest. According to the manufacturer's specifications, there is no influence on the test results by the differing colors.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report. The validity of this certificate applies only to the above mentioned product in this particular condition. For further information visit our website at www.ipa-qualification.com.

Stuttgart, April 28, 2010

i. A.
Project manager

Forbo Flooring Systems is part of the Forbo Group, a global leader in flooring, bonding and movement systems and offers a full range of flooring products for both commercial and residential markets. High quality linoleum, vinyl, flocked and textile floors combine functionality, colour and design, giving you total flooring solutions for any environment.



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creating better environments



FLOORING SYSTEMS