

TRESPA® TOPLAB® in Cleanroom

Training for partner use only



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TRESPA®

Trespa® TopLab® presentation content

- Definition and Standards
- TopLab® properties applied to Cleanrooms
- Particle emission
- Corrosion
- Decontamination
- Chemical resistance
- Electrostatic charges
- Cleanability
- Emissions (Outgassing)
- Certification for Cleanroom
- Standard Delivery Program
- Trespa® TopLab® in pictures...

Definitions and Standards

Cleanrooms

- **Cleanroom**

Room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

- **Particle concentration**

Number of individual particles per unit volume of air



Cleanrooms: main regulations

- Cleanroom classification **ISO 14644-1**
- EU Good Manufacturing Practice (**GMPs**)
Manufacture of Sterile Medicinal Products
- US-based **FED-STD-209 E** Airborne Particulate Cleanliness Classes in Cleanrooms and Cleanzones
- Fraunhofer considers also **VDI 2083** (Verein Deutschland Ingenieure) considerations



GMP (Good Manufacturing Practices) for medicinal products

Grade A	Grade B	Grade C	Grade D
<p>Sinks and drains prohibited in Grade A</p> <p>High-risk operations (filling zone, stopper bowls, open ampoules, and vials, making aseptic connections)</p> <p>Laminar airflow cabinet can obtain Grade A cleanliness in Grade B background</p> <p>Equivalent to an ISO 5 cleanroom environment (at rest and in operation)</p>	<p>Sinks and drains are prohibited in Grade B</p> <p>ISO 5 at rest, ISO 7 in operation</p> <p>Particle monitoring system with alarm if limits are exceeded is required</p> <p>Background zone for Grade A</p> <p>Used for aseptic preparation and filling</p>	<p>Less critical operations</p> <p>ISO 7 at rest, ISO 8 in operation</p> <p>Monitoring depends on the quality risk management</p> <p>Used for filling of products for terminal sterilization (at least in a Grade C)</p> <p>Preparation of solutions to be filtered, including weighing</p>	<p>Less critical operations</p> <p>ISO 8 at rest, not defined for in operation</p> <p>Dirtiest area of GMP guidelines</p>

- **Grade A:** The local zone for high risk operations
- **Grade B:** For aseptic preparation and filling
- **Grade C and D:** Clean areas for carrying out less critical stages in the manufacture of sterile products.

ISO 14644

The quality of the “clean production” system is decisively influenced by the materials used.

A controlled environment is specified using rules for the classification of air cleanliness (e.g. ISO 14644): these rules define the **sizes** and **concentrations** of airborne particles in the supply air.

Cleanroom suitability is part of compatibility with the required cleanliness and **deals with particle emission behaviour only.**

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (N)	Maximum allowable concentrations (particles/m ³) for particles equal to and greater than the considered sizes, shown below ^a					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	10 ^b	d	d	d	d	e
2	100	24 ^b	10 ^b	d	d	e
3	1 000	237	102	35 ^b	d	e
4	10 000	2 370	1 020	352	83 ^b	e
5	100 000	23 700	10 200	3 520	832	d, e, f
6	1 000 000	237 000	102 000	35 200	8 320	293
7	c	c	c	352 000	83 200	2 930
8	c	c	c	3 520 000	832 000	29 300
9g	c	c	c	35 200 000	8 320 000	293 000

^a All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.

^b These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see [Annex D](#).

^c Concentration limits are not applicable in this region of the table due to very high particle concentration.

^d Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

^e Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

^f In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See [C.7](#))

^g This class is only applicable for the in-operation state.

Table from classification of air cleanliness by particle concentration (ISO 14644-1:2015)

TopLab[®] properties applied to Cleanrooms

Cleanrooms: material properties

- Particle emission
 - Corrosion
 - Decontamination
 - Chemical resistance
 - Electrostatic charges
 - Cleanability
 - Emissions (Outgassing)
- Not all materials are good for every application; there is no perfect material that suits all cleanrooms.
- **However TopLab® PLUS and TopLab® VERTICAL have excellent properties for most cleanrooms application**

	Particles	Outgassing	ESD	Cleanability	Chemical resistance
Semiconductor industry	++	++	++	+	+
Microsystem engineering	++	+	++	+	+
Pharmaceutics	++	○	+	++	++
Biotechnology	+	+	○	++	++
Medical engineering	+	○	+	++	++
Photovoltaic industry, thin-film	+	+	+	○	○
Photovoltaic industry, poly-silicon	+	+	+	○	○
Food industry	+	+	○	++	++

++ mandatory

+ recommended, but not mandatory

○ not generally required, individual check recommended

Particle emission

- It is responsibility of who designs the cleanroom to assess suitability of material for type of cleanroom; refer to norm 14644,
- Suitability of Trespa **TopLab**® in cleanrooms depends on type of stress and use
- Since the material is made of paper/wood, it is not suitable for cleanest cleanrooms (GMP class A and ISO class 1 to 4)
- **We can provide references from experience using TopLab® in :**
 - **GMP class B / C / D**
 - **ISO class 5 to 9**

Corrosion

- The sodium hypochlorite in **bleach** reacts with carbon dioxide in the air to produce chlorine gas, a powerful oxidizer that will attack most metals, including the chromium oxide layer on the stainless steel
- **TopLab[®] material is not made from metal and therefore does not corrode**

Decontamination H₂O₂ (for sterile production)

- Controlled environments for sterile production require regular decontamination.
- The use of **vaporized hydrogen peroxide (H₂O₂)** to decontaminate controlled environments is the preferred method.
- Each decontamination cycle ends with an aeration phase to reduce the vaporized hydrogen peroxide to a specified limit.
- **Decontamination – Fraunhofer test demonstrate that desorption of H₂O₂ on TopLab[®] PLUS is fast (average below 13 minutes) and reach on average 17 minutes for TopLab[®] VERTICAL**

Chemical resistance

- Different test methodologies exist with different duration; concentrations; cleaning & testing procedure

- Most common methodologies are from EN438; SEFA and FRAUNHOFER

- **TopLab® PLUS and TopLab® VERTICAL show excellent results with most chemicals and up**

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

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	excellent
Hydrochloric acid 5 %	excellent	excellent	excellent	excellent
Isopropanol 100 %	excellent	excellent	excellent	excellent
Sodium hydroxide 5 %	excellent	excellent	excellent	excellent
Sodium hypochlorite 5 %	excellent	excellent	excellent	excellent
CSM classification				excellent

SGS Test Report

Tests:

Test No.	Chemical	Method	Rating	Comments
1	Formalin 37%	A	5	
2	Ammoniac 25%	A	4	
3	Hydrogen peroxide 30%	A	5	
4	Sulfuric acid 5%	A	5	
5	Phosphoric acid 30%	A	5	
6	Peracetic acid 15%	A	5	
7	Hydrochloric acid 5%	A	5	
8	Isopropanol 100%	A	5	
9	Sodium hydroxide 5%	A	4	
10	Sodium hypochlorite 5%	A	5	
11	Control	A	5	

SGS Test Report

Tests:

Test No.	Chemical	Method	Rating	Comments
1	Formalin 37%	A	5	
2	Ammoniac 25%	A	4	
3	Hydrogen peroxide 30%	A	5	
4	Sulfuric acid 5%	A	5	
5	Phosphoric acid 30%	A	5	
6	Peracetic acid 15%	A	5	
7	Hydrochloric acid 5%	A	5	
8	Isopropanol 100%	A	5	
9	Sodium hydroxide 5%	A	4	
10	Sodium hypochlorite 5%	A	5	
11	Control	A	5	

Example of test result from Fraunhofer IIS

Example of SEFA test result from SGS

Electrostatic characteristics

- The **resistivity** is the capability of dissipating any existing charge in a controlled manner and sufficiently rapidly. The **conductivity** of a material depends on its resistivity: the higher the resistivity, the lower the conductivity. A distinction is made between antistatic, static conductive or static dissipative and insulating materials.

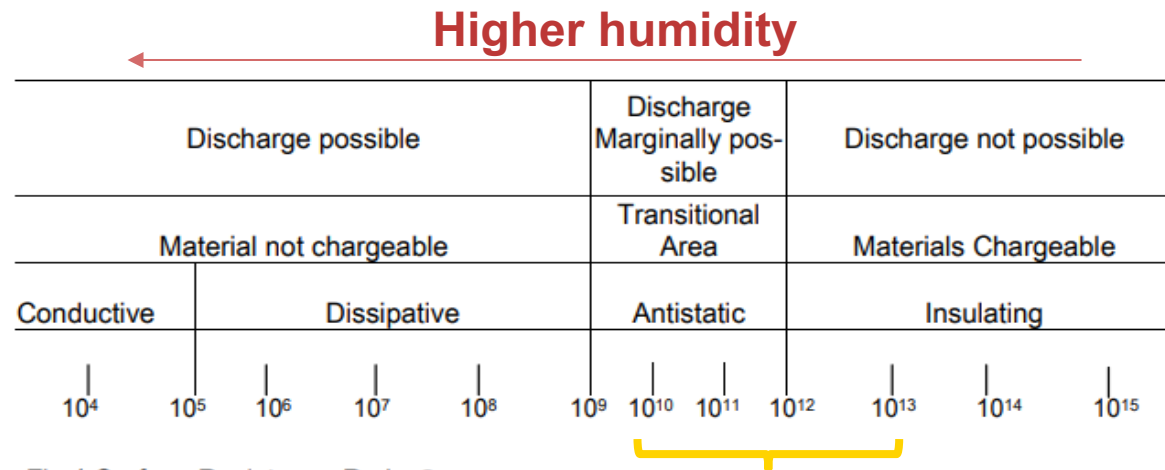


Fig.1: Surface Resistance R_o in Ω

TopLab PLUS Calculated at: 23°C & 20% RH

- Depending on operating conditions TopLab® material is Antistatic ($10^{10} \Omega$) and could be also Insulating ($10^{13} \Omega$)

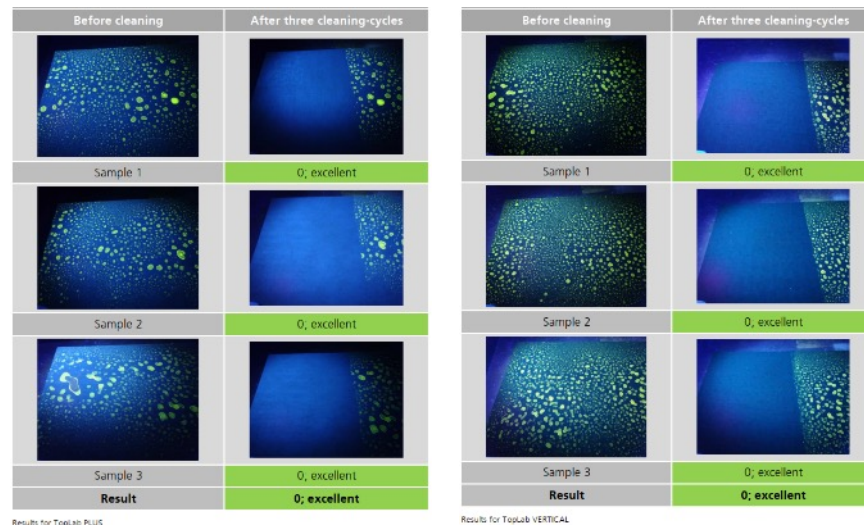
Cleanability – Fraunhofer Riboflavin test

- **What is it?**

A fluorescence test is performed to check the cleanability of the surface. This test method is of great relevance, especially in the field of sterile process engineering. By applying a test liquid to the test object and performing a defined cleaning procedure, the residues on the product can be evaluated.

- **How?**

https://www.youtube.com/watch?v=L_SwPbgQ8I0&t=88s



- **Both, TopLab® PLUS and TopLab® VERTICAL score EXCELLENT at the Fraunhofer Riboflavin test**

Outgassing documentation

- The quantity of organic compounds outgassed from materials depends upon surface area, outgassing time, age of the material and test temperature
- There are several methodologies to calculate formaldehyde/VOC/SVOC emissions: MPD; GREENGUARD; FRAUNHOFER...
- **Test Results for TopLab® PLUS and TopLab® VERTICAL show excellent performance:**

Greenguard Gold certification



Fraunhofer results:

Contaminant Category (x)	SER _a ¹⁾ 23 °C [g/m ² s]	SER _a ¹⁾ 90 °C [g/m ² s]	ISO-ACC _m C-class (x) based on 23 °C
VOC	8.6 x 10 ⁻⁹	6.1 x 10 ⁻⁸	-8.1
SVOC	< 2.8 x 10 ⁻¹⁰	< 1.7 x 10 ⁻⁹	< -9.6
Amines	< 2.8 x 10 ⁻¹⁰	< 1.7 x 10 ⁻⁹	--
Organophosphates	< 2.8 x 10 ⁻¹⁰	< 1.7 x 10 ⁻⁹	--
Siloxanes	< 2.8 x 10 ⁻¹⁰	< 1.7 x 10 ⁻⁹	--
Phthalates	< 2.8 x 10 ⁻¹⁰	< 1.7 x 10 ⁻⁹	--

Trespa® TopLab® Certifications for Cleanroom

Certification for Cleanroom

Main certification available related to cleanroom application:

- Franhofer Qualification test for Outgassing SVOC/VOC, Ammonia, Inorganic Acid; Chemical resistance; Riboflavin,
- Test certification from manufacturers of cleaning agent: Steris, Virkon, Shuelke, Eco-point...
- Greenguard & vGreenguard Gold
- SEFA-3 and SEFA_8



Trespa® TopLab® Standard Delivery Program

Standard Delivery Program: TopLab®VERTICAL

- The widest range of **Exclusive decors** (*Metallics, Lumen*) and texture
- Available in **4 ideal formats** to reduce cutting waste

3 TYPES

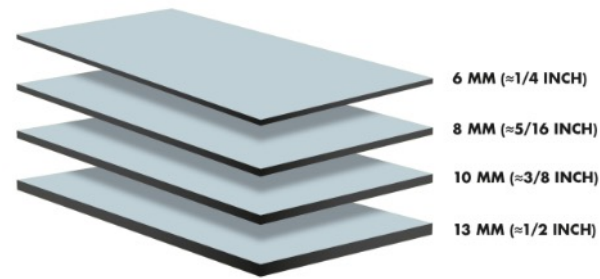
SINGLE SIDED DECORATIVE

DOUBLE-SIDED DECORATIVE

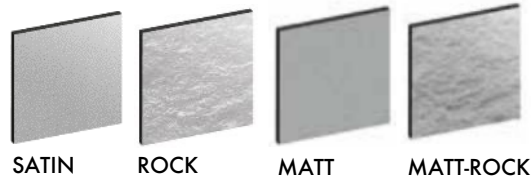
DUOCOLOR



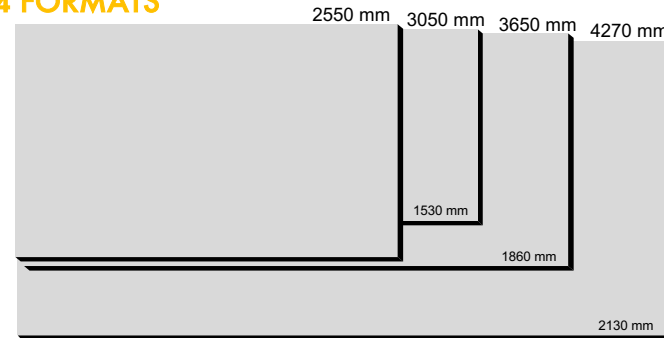
4 THICKNESSES



4 TEXTURES



4 FORMATS



100+ DECORS



Standard Delivery Program: TopLab®PLUS

- A large choice of colors for worktops
- Produced in **3 ideal formats** to reduce cutting waste
- Available also with the highest amount of Bio-based content (**up to 85%**)

3 TYPES

SINGLE SIDED
DECORATIVE



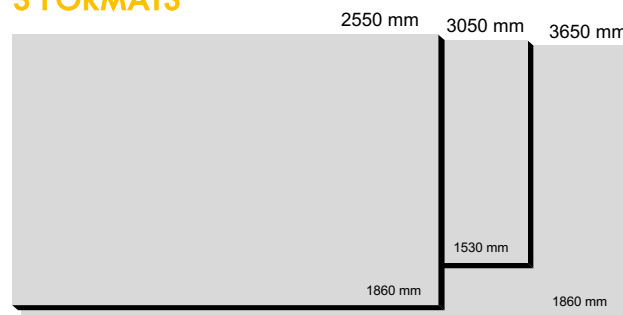
DOUBLE-SIDED
DECORATIVE



DUOCOLOR



3 FORMATS



4 THICKNESSES



13 MM (≈1/2 INCH)

16 MM (≈5/8 INCH)

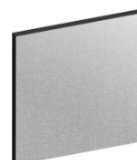
20 MM (≈3/4 INCH)


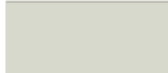
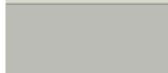
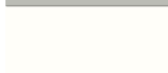

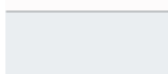
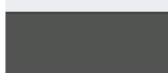


25 MM (≈1 INCH)

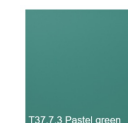
* GREY CORE: 13, 19, 25 MM

1 TEXTURE

CRYSTAL-MATT



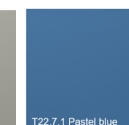
	T03.0.0	White
	T03.1.0	Pastel Grey
	T03.4.0	Silver Grey
	T05.0.0	Pure White
	T18.0.1	Mystic White
	T21.1.1	Glacier Blue
	T70.0.0	Slate Grey
	T90.0.0	Black
	D02.1.0	Pastel Grey/Silver



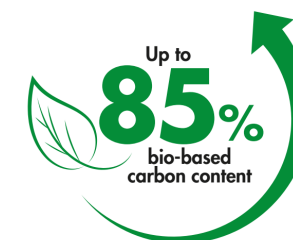
T37.7.3 Pastel green



T07.4.8 Mid greige



T22.7.1 Pastel blue



Trespa® TopLab® in pictures

(because 1 image is sometimes better than 100 words...)













Think Trespa