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Made for people.

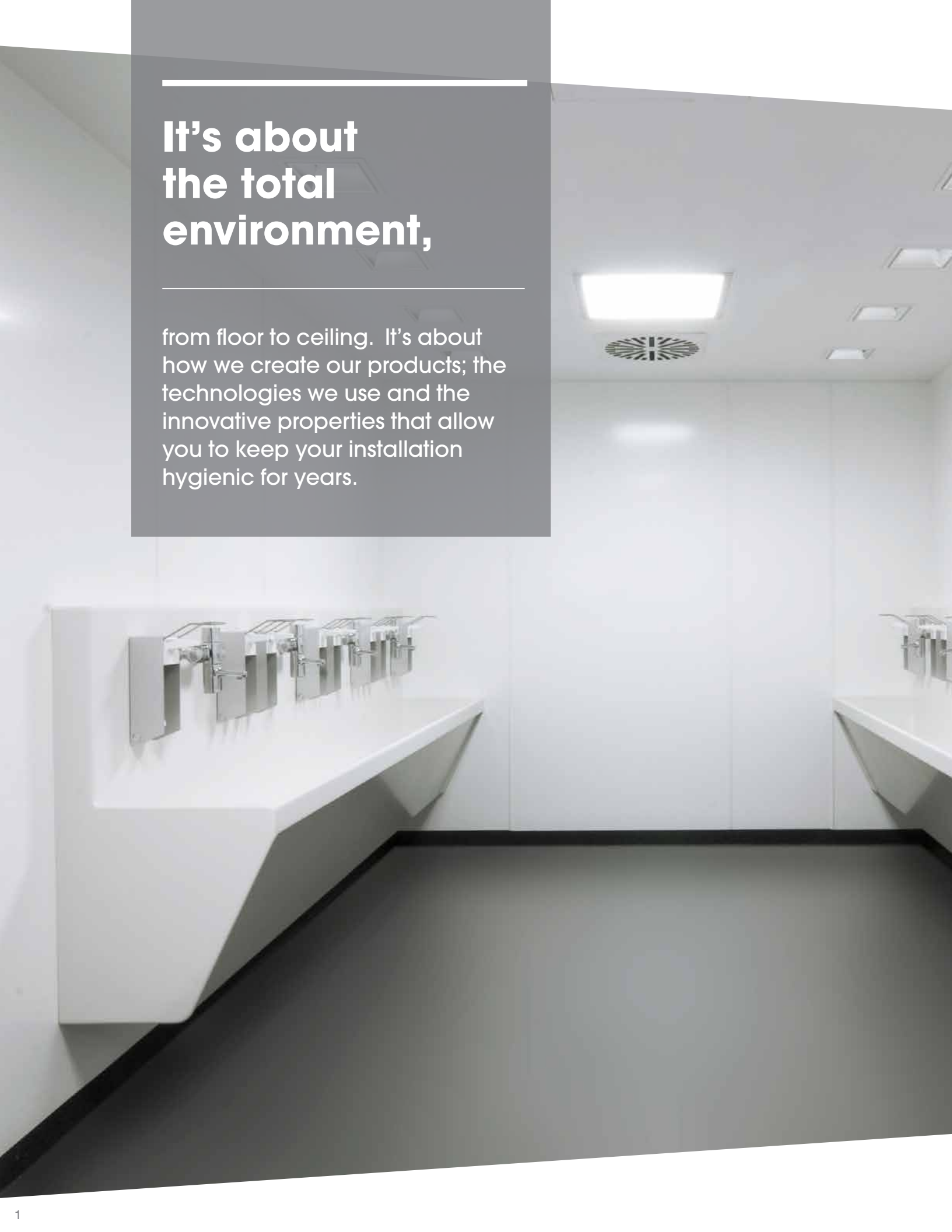


Floor and wall finishes for laboratories and cleanrooms

Guidebook for USP 797 and USP 800 compliance

It's about the total environment,

from floor to ceiling. It's about how we create our products; the technologies we use and the innovative properties that allow you to keep your installation hygienic for years.





Achieve USP 797 + USP 800 compliance with floor and wall solutions from Altro

Made effective in 2019, USP 800 introduces multiple new requirements for pharmacies. Introducing multiple new requirements for pharmacies, the new legislation is intended to protect pharmacists, nurses, pharmacy technicians, and others from the potential carcinogenic and teratogenic effects of hazardous drugs (HDs).

Your business is to develop and deliver safe and effective pharmaceuticals to the marketplace. Our business is to provide you with durable, hygienic interior finishes that will support your work. Protect your personnel with a safer environment to handle chemotherapy medications and other hazardous drugs by achieving USP 797 + USP 800 compliance with Altro's hygienic floor and wall system.

If you act last-minute to comply with the new legislation, you risk a slew of disruptive effects, including increased costs, inopportune facility downtime, federal litigation, and more. Minimize your risk by taking early, proactive steps to be compliant with USP 800.

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USP 797 regulations

Standards for compounding sterile preparations help promote patient safety and prevent harm

USP (United States Pharmacopeia) 797 is a comprehensive regulation applying to institutions within healthcare and pharmaceutical industries where sterile compounds are prepared, stored and dispensed. The purpose of the regulation is to prevent infections in patients using pharmaceutical products, as well as to protect pharmacy staff members that are ordinarily exposed to pharmaceutical products.

The legislation affects facilities in which sterile products are prepared or compounded according to the manufacturer's labeling and instructions.

Typical facilities affected by USP 797

- Laboratories
- Pharmaceutical manufacturing plants
- Compounding facilities
- Hospitals
- Pharmacies

Requirements of floors and walls

- ✓ Surfaces of ceilings, walls and floors shall be smooth, impervious, free from cracks and crevices and non-shedding – required to meet ISO Class cleanrooms
- ✓ Surfaces must be resistant to damage by disinfectant agents
- ✓ **Preferably, floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall**

Areas must meet a range of ISO Cleanroom compliance for the area they will be installed

- ✓ ISO Class 5 for Critical Areas
 - ✓ Segregated compounding areas
 - ✓ Aseptic processing rooms
 - ✓ Primary engineering control rooms
- ✓ ISO Class 7 for buffer zones and low risk compounding areas
- ✓ ISO Class 8 for ante-areas





USP 800: ensuring compliance

Information, updates and resources for the safe handling of hazardous drugs

In March of 2014 the United States Pharmacopeial Convention proposed new general chapter referred to as USP 800. This new chapter applies to all personnel that compound hazardous drug (HD) preparations, as well as all places where hazardous drugs are prepared, stored, transported and administered in order to protect healthcare workers, patients and the environment.

In the nearly two years since its initial publication in draft form, USP 800 has undergone periods of public comment and revision. Following these revisions, the chapter was approved and became effective for compounding and pharmaceutical facilities in 2019.


Due to provisions, USP 800 is being legally enforceable and may subject pharmacies to both state board and FDA inspections.

This means facilities must comply with the requirements of USP 800 or they risk being shut down until these standards are met.

Path to compliance

Whether you're looking to build a cleanroom or a negative-pressure compounding area, Altro can help. Altro manufactures products that can help facilities achieve USP 800 compliance.

We offer a floor and wall solution that is seamless, non-shedding, and heat-weldable. Our solution offers the right amount of hygiene and performance and is well suited for USP regulated facilities.



i Did you know?

Facilities must comply with the requirements of USP 800 or they risk being shut down until these standards are met.

Integrated floor + wall solution

Altro offers a complete floor and wall solution. It's an integrated solution, which means it fits together perfectly to provide a hygienic, watertight surface. This doesn't just offer the best possible protection against bacteria and contamination; it makes cleaning easy too.

Our integrated floor and wall solution is designed to provide a completely sealed environment from floor to ceiling and has been engineered to work together: the joined surfaces stay that way – joined. This gives you peace of mind that the surfaces will stay hygienically sealed.

Consistent quality

Altro products are always made from the finest materials, which are consistent in grade and color across every sheet, batch, and joint to provide uniform high performance and ensuring compatibility between product lines.

Easy to keep clean

Used together, our products provide a robust, hard-wearing surface that resists stains, odors and chemicals. PVC is non-porous, non-shedding, and has very high impact resistance, preventing damage that can trap bacteria compared to traditional surfaces. Altro flooring and wall panels are also cGMP compliant, meaning that their enhanced cleanability ensures that pharmaceuticals produced in facilities equipped with them are safe for use by consumers.

Effective detailing

We know the devil's in the details. That's why our products have been constructed to maintain their integrity, meet the strictest hygiene standards, and to provide a perfect fit with no gaps or rough edges around joints and details — maintaining excellent hygiene becomes a whole lot easier with Altro.

Fully sealed

Altro Whiterock is a fully-bonded system with hygienic sealed edges, abutments and joints. It can even be sealed around pipes, ventilation outlets, light switches, plug sockets, and other fixtures and fittings.

Our floors are also fully sealed. When joined together with Altro Whiterock, they form a watertight covering - from floor to ceiling.

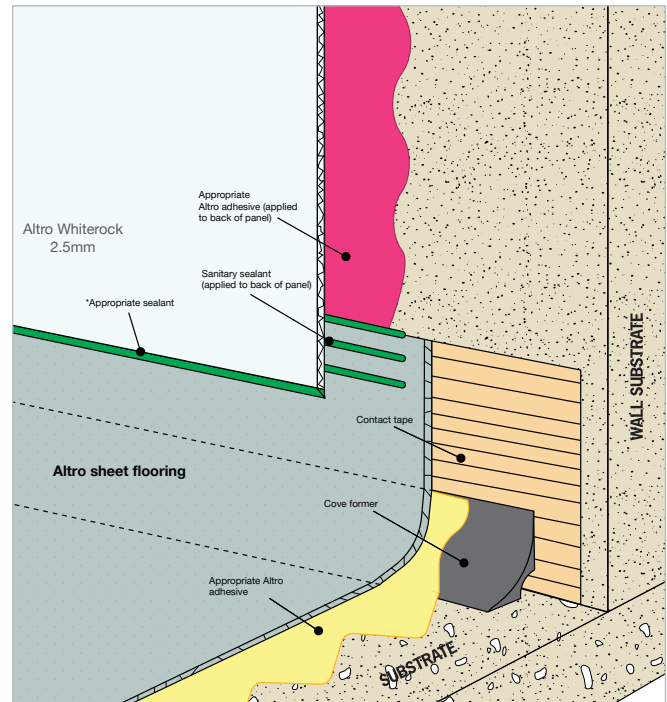
Thermoforming

Because our wall panels are thermoformed around internal and external corners on-site, they form an uninterrupted surface that's resistant to impact and damage. There's no need for unsightly corner trims which can form potential dirt traps that are difficult to access and clean.

Joint forces

Joints and junctions are a key part of system integrity. While we have multiple joining methods, in sterile areas Altro recommends heat welding for all joints - both wall panel to wall panel and wall to floor.

Detail diagram of a floor to wall overlap transition to the Altro Whiterock panel, this installation method offers enhanced security over water ingress.



Heatwelding Altro Whiterock panels together



floor + wall



Did you know?

Installing Altro Whiterock and Altro flooring with heatwelded joints creates a hygienic, fully sealed environment. Perfect for labs, cleanrooms, compounding areas, buffer zones, and ante-areas.

Altro Whiterock™

ISO Class 2 and above
cleanroom requirements



Interior finishes, such as wall paneling, are under close scrutiny in sterile application areas. Regulation requires that finishes must be smooth, non-porous, non-shedding, easy to clean and resistant to chemicals and staining. They must be installed seamlessly to prevent cracks, gaps and fissures.

Altro Whiterock's smooth, durable, hygienic, and easy-to-clean surface can help you meet demanding regulatory requirements, maximize your production time, and ultimately increase your speed to market — with no surprises along the way.


As it meets ISO Class 2 and above cleanroom requirements, Altro Whiterock can be installed in even the most stringently controlled environments.








Once installed, Altro Whiterock wall panels are heat welded together using a color matched vinyl weldrod. This process creates a smooth, seamless surface that ensures there is no place to harbor contaminants.

- 2.5mm thick
- 4' x 8' and 4' x 10' panels
- 20-year warranty
- White or color panels available
- Stain resistant
- Low VOC emitting
- Meets ISO Class 2 cleanroom requirements

walls



Thickness	2.5mm .10"	
Dimensions	8' - 4' x 8' 2" 1.22m x 2.5m 10' - 4' x 9' 10" 1.22m x 3.0m	
Weight	8' panel - 23.59 lbs 10.7 kg 10' panel - 28.22 lbs 12.8 kg	
Warranty		20 years
Fire and smoke performance	CAN/ULC-S102.1 CAN/ULC-S102.2 ASTM E84-08	Tested Tested Class A
Impact resistance	ASTM D5420	Up to 198 inch lbs in force
VOC emissions	CA 01350	Pass
Particle concentration	ISO 14644-1:12	Meets ISO Class 2 cleanroom
Max service temperature	140°F (60°C)	
Tensile strength (Mpa)	ISO 527	48
Surface resistance ROE (Ω)	DIN IEC 60 167	2.00E +14
Dielectric strength (kV/mm)	DIN IEC 243	16.8
Dielectric loss index	DIN 53483	0.02
"U Value" bonded to 100mm block wall (W/m² °C)	DIN 52612	1.8
Compressive strength (N/mm²)	DIN 53454	70
Water absorption	ISO 62	24 hrs - .030% 168 hrs - .093% 216 hours - .106%
UV exposure	ASTM G154	Tested

	Altro Whiterock is USDA compliant	
	Altro Whiterock is FDA compliant	
	Altro Whiterock conforms to the hygienic standards of USP 797	
	Altro Whiterock is CFIA compliant	
	HACCP International certified	
Density (g/cm3)	ISO 1183	1.39
Flexural strength (Mpa)	ISO 178	79.8
Shore hardness, Type D	ISO 868	79
Volume resistance RD (Ω)	DIN IEC 60 093	6.90E+13
Dielectric constant	DIN 53483	3.2
Thermal conductivity - "K Value" (W/mK)	DIN 52612	0.16
Coefficient of linear thermal expansion	DIN 53752	7.10-5 at 68°F (20°C) after 1 hr storage at 194°F (90°C) (104/K)
Vicat softening point VST/B	ISO 306	176°F (80°C)
Heat distortion temperature	ISO 75-2	140°F (60°C)
	Fungi resistance ASTM G21	Passes rating 0* *achieves zero growth after 21 days
	Mold resistance ASTM D3273	Excellent Score of 10

Meets the following requirements

- Smooth
- Impervious
- Free from cracks
- Non-shedding
- Resistant to disinfectants
- Able to seal at ceiling
- Able to heatweld
- Combines with Altro flooring

Features and benefits

- Class A fire rated
- Consistent 2.5mm thickness
- Heat welded seams
- Fully bonded to substrate
- Impervious to water ingress
- Surface does not promote bacterial or fungal growth
- Extremely impact resistant
- Highly stain and chemical resistant
- Withstands robust cleaning procedures including pressure washing
- Non-porous, hydrophobic
- Non-shedding
- No VOCs
- Lead free
- Internal and external preformed corner accessories available
- Thermoformable on site



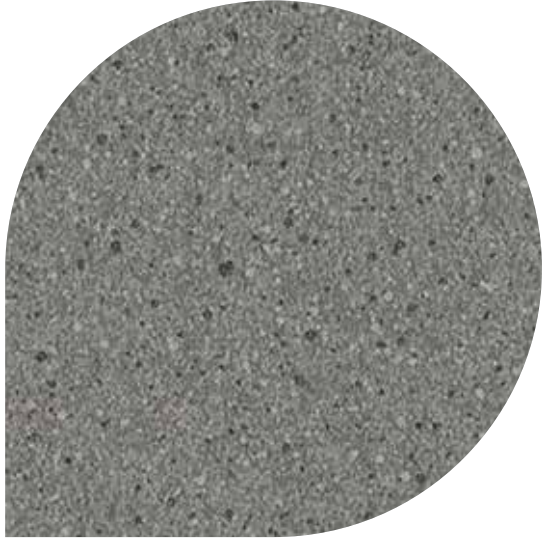


Did you know?

Altro Whiterock was the first hygienic wall system. We invented it back in 1982, to install seamlessly with our flooring.

Altro Operetta™

ISO Class 4 cleanroom



Altro Operetta is a robust floor perfect for medium to high traffic areas. It is easy to clean and maintain.

The product boasts a surface profile that is smooth, impervious, free from cracks and crevices, and non-shedding. Built with Altro Easyclean surface technology, Altro Operetta is resistant to disinfectant and other cleaning agents.

Combine with Altro Whiterock wall panels for areas requiring a seamless, floor-to-ceiling, hygienic surface.

- 2mm thick
- 2m wide
- Withstands 2000psi
- 10-year warranty
- 25 colors
- Stain-resistant
- Low-VOC emitting
- Meets ISO Class 4 cleanroom requirements
- Non-toxic, non-polluting, no heavy metals



floors

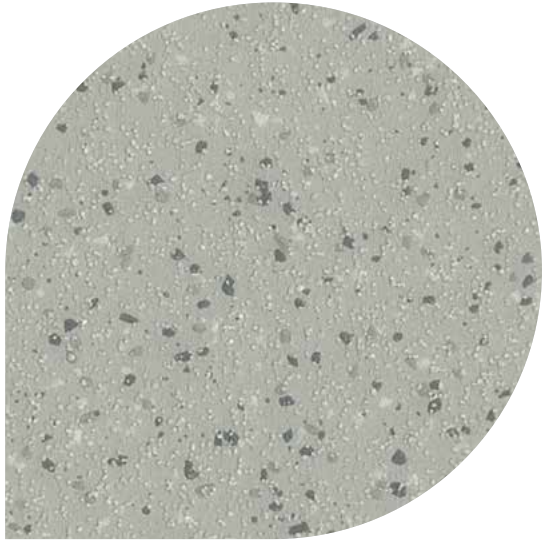
Warranty		10 years	
Cleaning technology		Altro Easyclean	
Static coefficient of friction		ASTM D2047	.7 dry, .8 wet
Dynamic coefficient of friction		ANSI/NFSI B101.3	.49 wet DCOF
Ramp test		DIN 51130	R10
Static load limit		ASTM F970	2000 psi
Indentation		EN 433	≤ 0.10mm
Wear (abrasion) resistance		EN 660	≤ 10% 50,000 cycles
Castor chair abrasion		EN 425	Pass
Flexibility		EN ISO 24344	Pass
Light fastness		EN 20105-B02	≥ 6
Sound insulation		ISO 140-8	4dB
Electrical behaviors		EN 1815	≤ 2kV Antistatic
Fire and smoke performance		CAN/ULC - S102.2 ASTM E648 ASTM E662	Tested Class I < 450
Mold resistance		ASTM D3273	Excellent - Score of 10
Fungi resistance		ASTM G21	Passes rating 0* *achieves zero growth after 28 days
Chemical resistance		ASTM F925	Tested
Particle concentration	ISO 14644 - 9:12	Meets ISO 4 cleanroom requirements	
VOC emissions		CA 01350 FloorScore	Pass Certified
Bio-based content		Manufactured with rapidly renewable bio-based content.	
Ortho-phthalate content		Ortho-phthalate-free	

Meets the following requirements

- Smooth
- Impervious
- Free from cracks
- Non-shedding
- Resistant to disinfectants
- Able to cove
- Able to heatweld
- Combines with Altro Whiterock wall system

Altro Symphonia™

ISO Class 4 cleanroom



Bold, bright and beautiful - Altro Symphonia was engineered to deliver striking looks and bridge the gap between smooth and slip resistant flooring.

Altro Symphonia is smooth to the touch and easy to clean yet will secretly enhance pedestrian safety.

The product is impervious, free from cracks and crevices, and non-shedding. Built with Altro Easyclean surface technology, Altro Symphonia is resistant to disinfectants and other cleaning agents.

Combine with Altro Whiterock wall panels for areas requiring a seamless, floor-to-ceiling, hygienic surface.

- 2mm thick
- 2m wide
- Withstands 2000psi
- 10-year warranty
- 41 colors
- Enhanced slip resistance values
- Stain-resistant
- Low-VOC emitting
- Meets ISO Class 4 cleanroom requirements
- Non-toxic, non-polluting, no heavy metals

floors



Warranty		10 years	
Cleaning technology		Altro Easyclean	
Static coefficient of friction		ASTM D2047	.8 dry, .9 wet
Dynamic coefficient of friction		ANSI/NFSI B101.3	.38 wet DCOF
Ramp test		DIN 51130	R10
Static load limit		ASTM F970	2000 psi
Indentation		EN 433	≤ 0.10mm
Wear (abrasion) resistance		EN 660	≤ 10% 50,000 cycles
Castor chair abrasion		EN 425	Pass
Flexibility		ASTM F137	Pass
Light fastness		EN 20105-B02	≥ 6
Sound insulation		ISO 140-8	5dB
Electrical behaviors		EN 1815	≤ 2kV Antistatic
Minimum operating temperature		-4°F (-20°C)	
Fire and smoke performance		CAN/ULC - S102.2 ASTM E648 ASTM E662	Tested Class I < 450
Chemical resistance		EN 423	Tested
Particle concentration	ISO 14644 - 9:12	Meets ISO 4 cleanroom requirements	
VOC emissions		CA 01350 FloorScore	Pass Certified
Bio-based content		Manufactured with rapidly renewable bio-based content.	
Ortho-phthalate content		Ortho-phthalate-free	

Meets the following requirements

- Smooth
- Impervious
- Free from cracks
- Non-shedding
- Resistant to disinfectants
- Able to cove
- Able to heatweld
- Provides slip resistance
- Combines with Altro Whiterock wall system

Stain resistance

Floors and walls in clean facilities are constantly exposed to a barrage of aggressive chemicals. Surfaces see everything from decontaminants to germicidal cleaners and disinfectants. It is important your facility is furnished with materials that will stand up to these powerful agents.

We have tested our floor and wall products against many of the commonly used chemicals: such as sodium hypochlorite, phenolic disinfectants, and germicidal cleaners like Preempt and Simple Green D. You'll see the results here. For a full report, please visit our website.

Even with this, it is still very important that maintenance teams are well educated on how to properly care for the floor and walls in a facility.

Steps to reduce staining

- Select interior finishes that incorporate enhanced stain defense technology, like Altro
- Specify colors appropriate for the application area
- Use manufacturer recommended cleaners
- Train maintenance staff on proper care and cleaning procedures
- Make critical staining areas in a darker color that can be pulled up and replaced if necessary

In areas subject to significant exposure, an additional stain resistant coating* can be applied on site, to greatly increase the floor's resistance to chemicals.

*Example coating is MARKNOMOR by Dr. Shutz

Test result values	
No change	0
Slight change	1
Moderate change	2
Severe change	3

Altro Symphonia stain results

Chemical	Chemical resistance	Stain resistance after 24 hrs
Preempt RTU™ (hydrogen peroxide based)	0	1
Simple Green D Cleaner® (Didecyl dimethyl ammonium chloride)	0	0
Sodium Hypochlorite	0	0
Bleach	0	0
Phenol disinfectant	0	0
Hydrogen Chloride (HCl)	0	0
Isopropyl alcohol	0	0
Sulfuric Acid (H2SO4)	0	0
Hydrochloric Acid	0	0
Betadine® (Povidone-iodine 10%)	0	1

Altro Operetta stain results

Chemical	Chemical resistance	Stain resistance after 24 hrs
Preempt RTU™ (hydrogen peroxide based)	0	1
Simple Green D Cleaner® (Didecyl dimethyl ammonium chloride)	0	0
Sodium Hypochlorite	0	1
Bleach	0	0
Phenol disinfectant	0	1
Hydrogen Chloride (HCl)	0	0
Isopropyl alcohol	0	0
Sulfuric Acid (H2SO4)	0	0
Hydrochloric Acid	0	1
Betadine® (Povidone-iodine 10%)	0	1

Altro Whiterock stain results

Chemical	Chemical resistance	Stain resistance after 24 hrs
Preempt RTU™ (hydrogen peroxide based)	0	0
Simple Green D Cleaner® (Didecyl dimethyl ammonium chloride)	0	0
Sodium Hypochlorite	0	0
Bleach	0	0
Phenol disinfectant	0	1
Hydrogen Chloride (HCl)	0	0
Isopropyl alcohol	0	0
Sulfuric Acid (H2SO4)	0	0
Hydrochloric Acid	0	1
Betadine® (Povidone-iodine 10%)	0	0
Ecolab™	0	0
Trichlorethene	0	0

Wall maintenance

Recommended cleaners/disinfectants for Altro Whiterock

To meet demanding regulatory requirements, a well-planned program to disinfect a variety of surfaces in order to maintain microbial control is critical.

We have conducted extensive testing on some of the most commonly used cleaners and disinfectants provided by **Steris Corporation.

- PVC wall cleaner (Altro)
- AltroClean 44
- **Spor-Klenz®
- **Vesphene® Ilse
- **LpH® se
- **CIP 200®

Samples were tested with these Steris cleaners at various dilution rates with water. The drying process of these chemicals typically takes 10 minutes, however, in these tests, the sample exposure was obtained by full immersion in the chemical for seven days. These extreme measures were taken to represent a worst case scenario. In all scenarios, with all chemicals, Altro Whiterock performed extremely well.

Initial cleaning

Once all panels and joints are installed, remove the protective film and clean all surfaces down with an anti-static solution or anti-static wipes. This is required as the panel may have static build up and any dust in the atmosphere will adhere to the surface of the panel.

Regular cleaning

- Altro Whiterock can be cleaned with a diluted soap/detergent solution, such as PVC wall cleaner (for stubborn stains) or AltroClean 44 (degreaser).
- Use a lint-free, non-woven wipe or a polyester knit wipe. Both are extremely low in particle generation.
- When cleaning Altro Whiterock's surface, we recommend the temperature of water does not exceed 140°F (60°C).
- Pressure cleaning with hot water may be used with the pressure nozzle, a minimum of 2 feet (600mm) away from the surface.
- To reduce the buildup of static, regularly cleaning the panels with an anti-static solution or anti-static wipes is recommended.
- Some cleaning agents may adversely affect Altro Whiterock. See the full chemical resistance chart on our website altro.com/downloads.
- Do not use materials containing abrasives or solvents.

Floor maintenance

USP regulations contain specific maintenance parameters for flooring used in labs and cleanrooms. These stringent hygienic guidelines intend to prevent the spread of contaminants while ensuring that the space is safe for handling pharmaceutical compounds.

- Dedicated cleaning materials for each individual area
- Non-shedding, lint-free and 100% synthetic materials
- Consistent scrubbing patterns with unidirectional strokes, avoid erratic circular motions

Initial maintenance

1. Do not begin any maintenance procedure for at least 72 hours after installation.
2. Sweep or vacuum floor surface to remove all loose dust and debris.
3. Apply diluted* AltroClean 44™ to the floor. Allow to sit for five minutes to allow the cleaner to attack the surface soil.
4. Remove wash water with a wet vac or a synthetic floor mop using a double bucket
5. Ensure the floor is thoroughly rinsed with fresh, clean water. No cleaning residue should remain on the floor.
6. Allow surface to dry before use.

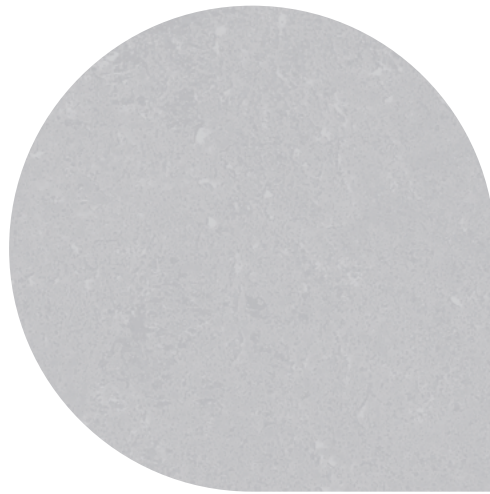
Routine maintenance

Mechanical cleaning is not recommended in these areas due to circular and erratic strokes. Manual cleaning in a unidirectional pattern is ideal in this sector.

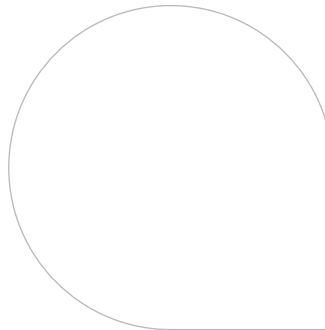
* Dilution rates depend on the condition of the floor. For moderate soiling use a 1:40 dilution ratio. For heavy soiling use 1:10.

For full cleaning and maintenance information, including illustrated cleaning guides, please refer to altro.com/techdocs

updated 06/29/21



Altro Operetta in Quartet



Altro Whiterock in Standard White



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