MEDICAL GRADE SOLUTIONS

Boltaron® Thermoplastic Materials

SIMONA boltaron

www.boltaron.com | +1 800 342 7444

RELIABILITY MEETS INNOVATION

Boltaron® Medical Grades

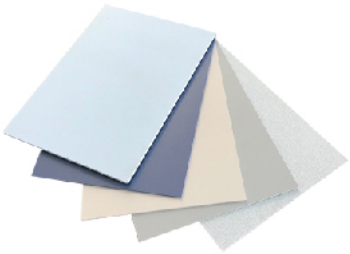
SIMONA Boltaron has several grades of high performance plastics to choose from for medical applications depending on your flammability, chemical resistance and processing requirements.

Characteristics

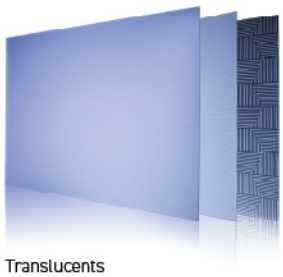
- High impact strength
- Durability
- Scratch resistant
- Can withstand harsh cleaners and chemicals
- UL 94 V-0 compliant
- Meets Class 1/A building code requirements
- Excellent thermoformability

Uses

- Medical device enclosures
- Orthotic braces
- Thermoformed electronic device enclosures
- Protective wall linings
- Hospital bed and lavatory components
- Diagnostic imaging
- In vitro diagnostic covers



Custom colors



Translucents

Metallic Effects

MATERIALS

Medical Grade	Flammability	Material
Boltaron® 4335	**UL 94 V-0, ASTM E-162**	**High Impact Thermoplastic Alloy**
Boltaron® 4205	UL 94 V-0	High Temperature Resistant, Ball Pressure
Boltaron® 6530	UL 94 V-0	Thermoplastic Alloy
Boltaron® 4300	UL 94 V-0	High Impact Clear PVC with a Transparent Blue Tint
Rigiwall® Boltaron® 4333	UL Standard 723 Listed, ASTM E84	Wall Covering Grade, Class 1/A Rated
Rigiwall® Boltaron® 4333W	UL Standard 723 Listed, ASTM E84	Wall Covering Grade, Class 1/A Rated and Corona Treated for Abrasion Resistance
Rigiwall® Boltaron® 4353	UL Standard 723 Listed, ASTM E84	Wall Covering Grade, Class 1/A Rated up to .125 in

BIOCOMPATIBILITY TEST

Medical Grade	Test (ISO 10993-5/10993-10)	Results
Boltaron® 4335	Intracutaneous Reactivity Test (IRT)	Certified
Boltaron® 4335	MTT Cytotoxicity Assay	Certified
Boltaron® 4335	Sensitization	Certified

For additional material solutions for the medical market available from SIMONA Boltaron, visit www.boltaron.com/medical

Boltaron® Antibacterial and Antifungal Properties

TESTING FOR RESISTANCE TO BACTERIAL AND FUNGAL DEVELOPMENT

Boltaron® thermoplastic sheet material does not support the growth of common bacteria and fungus under a variety of conditions. Refer to the results below for specific test results under ASTM G21 and G22 protocol. The tests conclude that Boltaron sheet materials perform well in preventing the growth of bacteria and fungus, even without the addition of an antimicrobial additive.

ASTM G21- RESISTANCE TO FUNGUS GROWTH

ASTM G21 is designed for the qualitative determination of mildew (fungus) resistance of synthetic polymeric materials. The method is conducted over a 28 day period by a third party lab, during which Boltaron sheet was placed in petri dishes on nutrient salts agar (in triplicate) and inoculated with the test fungi.

ORGANISM	TEST USED BY INOCULUM
Aspergillus Brasiliensis	ATCC 9642
Chaetomium Globosum	ATCC 6205
Penicillium Funiculosum	ATCC 11797
Trichoderma Virens	ATCC 9645
Aureobasidium Pullulans	ATCC 15233

CONCLUSION

The Boltaron sheet samples did not show any signs of fungus growth after four weeks.

ASTM G22- RESISTANCE TO BACTERIAL GROWTH

ASTM G22 is a qualitative test method designed to assess the ability of plastics to resist bacterial attack. The method is conducted over a 21 day period during which Boltaron sheet was placed on inoculated agar, incubated, and then compared to a positive and negative control.

The test microorganism used was Pseudomonas Aeruginosa. This is the most common disease-causing species, according to the Center for Disease Control and Prevention (CDC).

In this study, Tryptic Soy Agar was used as a positive control. This medium has no antimicrobial efficacy, and is known to support the growth of the test microorganism. The positive control confirmed the test microorganism was viable and pure. The negative control in this study used nutrient salt agar, which does not support bacterial growth. The negative control confirmed that it did not support the growth of the test microorganism. See below for results. The Boltaron sheet samples did not show any signs of bacterial growth after three weeks.

SAMPLE	INCUBATION (TIME AND GROWTH SCORE AT DAY 21)
Boltaron Sheet (Sample 1)	No Growth
Boltaron Sheet (Sample 2)	No Growth
Negative Control	No Growth
Positive Control	Growth

CONCLUSION

The Boltaron sheet samples did not show any signs of bacterial growth after three weeks.

ANTIBACTERIAL AND ANTIFUNGAL PROPERTIES

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RELIABILITY MEETS INNOVATION

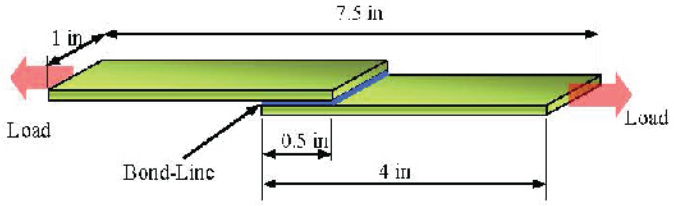
Fabricating Boltaron® 4335

BONDING AND THERMOFORMING RECOMMENDATIONS

Many types of adhesives can be used to glue or adhere Boltaron materials to a substrate. A study was performed to see which adhesives created a proper bond when adhered to a specific substrate. Types of adhesives that can be used include 2 part acrylics, contact cement, cyanoacrylates, foam acrylic tape, 2 part polyurethane, instant adhesives, multi-purpose cement, solvent based and structural adhesives. SIMONA Boltaron does not recommend the use of epoxy. For a complete list of **General Adhesive Guidelines**, visit: boltaron.com/careandmaintenance/adhesive-guidelines

Boltaron materials can be adhered to:

- Plywood
- Particle board
- Drywall
- Acrylic
- Cement board
- Polystyrene
- PVC
- Aluminum
- Stainless steel
- ABS



Schematic of a lap-shear specimen showing tensile loading

ADHESIVE TESTING – ASTM D3163 THEMOPLASTIC LAP SHEAR

Adhesive	Adhesive Manufacturer	Substrate	Lap Shear Avg.	Failure Mode
WO31	IPS Adhesives	Boltaron 4335	626.6 psi	100% substrate
WO45	IPS Adhesives	Boltaron 4335	615.2 psi	100% substrate
MA300	Plexus	Boltaron 4335	1540 psi	100% substrate
MA310	Plexus	Boltaron 4335	1525 psi	100% substrate
MA8110	Plexus	Boltaron 4335	1244 psi	100% substrate

SIMONA Boltaron recommends to verifying with the manufacturer for the best adhesive solution for a specific substrate.

IPSA chose the WO30 series and WO45 adhesives to be tested for bonding performance. ASTM 3163 – IPS Adhesives bonded rigid plastic lap-shear joints in shear by tension loading. Five lap shear each of WO30 series (WO31 used) and WO45 bonded Boltaron 4335. Adhesive bond dimensions per ASTM D3163: 1"x1"x0.03". Substrate per ASTM D3163: 4"x1".

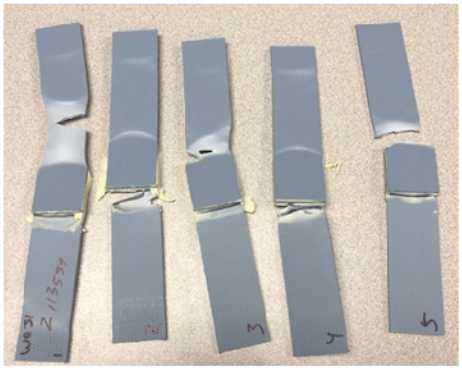
CONCLUSION

Both WO30 series (WO31 used for testing) and WO45 performed as expected on the Boltaron 4335 panels. All five WO31 bonded specimens resulted in the substrate breaking. All five WO45 bonded specimens resulted in the substrate breaking. With most of the test pieces, the Boltaron 4335 substrate deformed significantly, before breaking at ~620 psi.

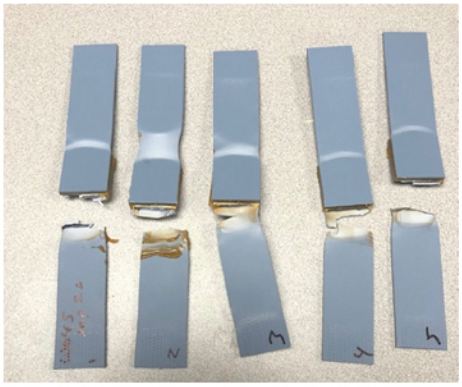
Please see pictures on the right for broken specimens.

As a result of testing, it was found that Plexus MA300, MA310 and MA8110 yielded the overall best performance for all plastics.

WO31 specimens



WO45 specimens



THERMOFORMING GUIDELINES

Mold Shrinkage	0.5 - 0.7%
Forming Temperature	335 - 370 °F (168 - 188 °C)
Typical Heater Settings	30 - 50% Top 50 - 70% Bottom
Drying	Not required

QUALITY GUARANTEE

SIMONA Boltaron is ISO 9001:2015 and AS9100 Rev D certified and maintains strict systems for quality control including management of sheet dimensions, color consistency, thermoforming surface appearance and material property stability using visual checks and in-house state-of-the-art testing equipment. For more information, visit www.boltaron.com/quality.

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Have a question about how to clean Boltaron® materials?
Call +1 800 342 7444, email info-boltaron@simona-group.com
or visit www.boltaron.com/care-and-maintenance