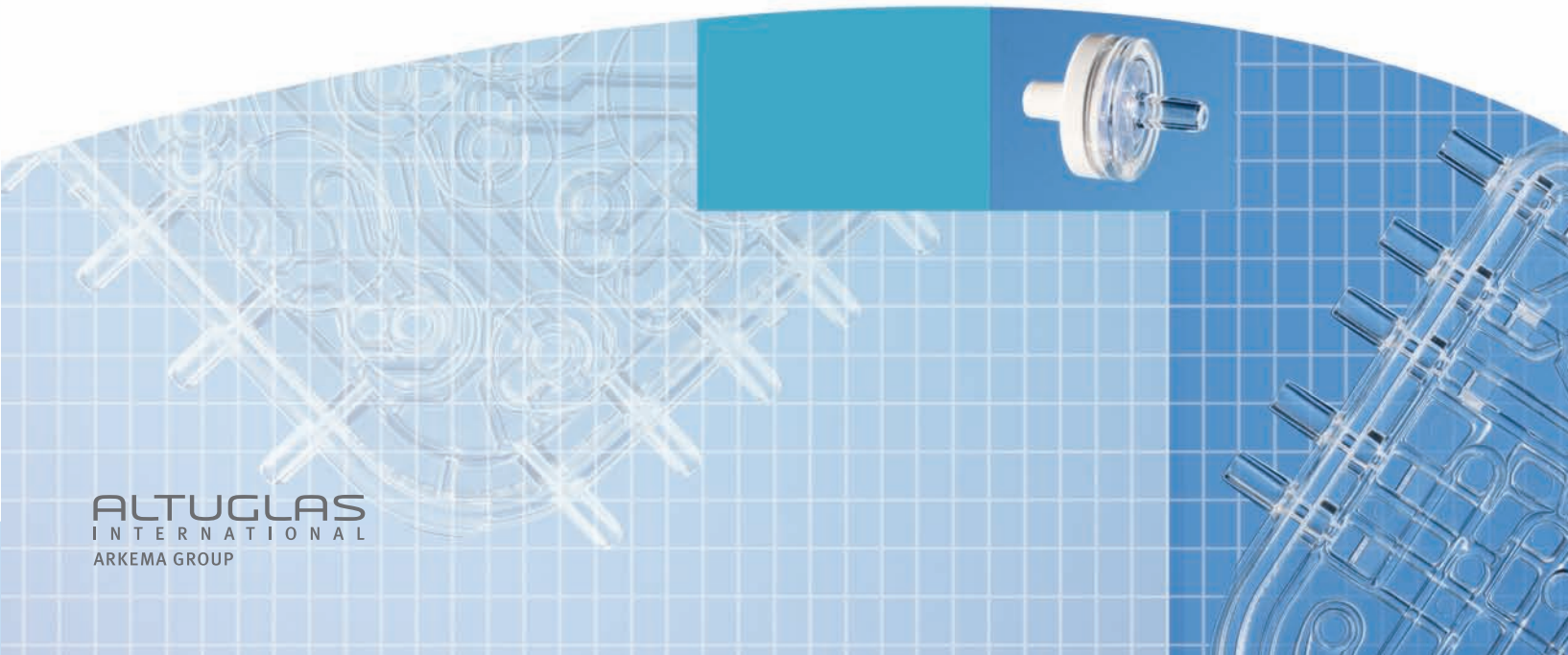
ACRYLIC RESINS

Altuglas® Medical Resins

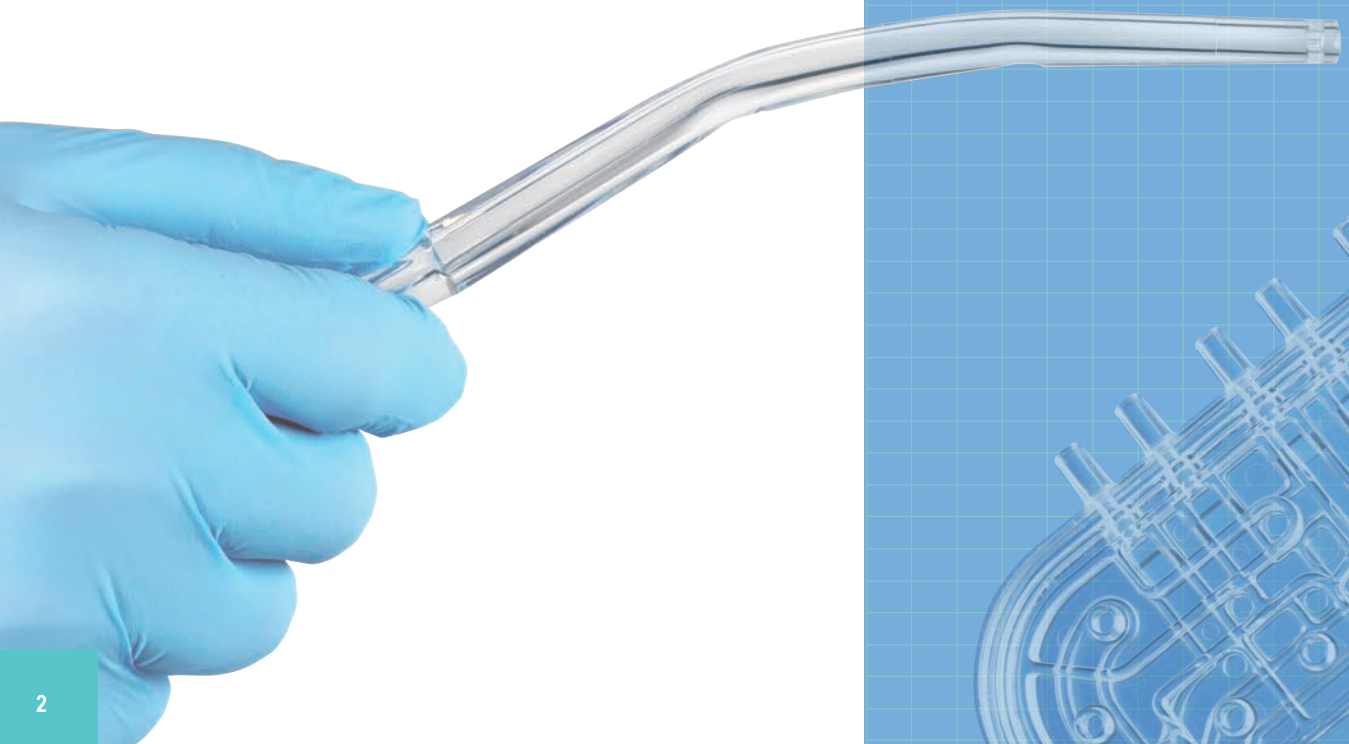
Altuglas®



ALTUGLAS
INTERNATIONAL
ARKEMA GROUP

As continual advances in drug design occur, medical disposable delivery systems increasingly require materials with greater chemical resistance. Simultaneously, health care providers seek devices that can perform longer, reducing the need for multiple replacements during treatments. It is incumbent upon materials suppliers to provide customers with products that meet these needs. For over 75 years, the Altuglas® resin family has provided such solutions through ingenuity and creativity to ensure that Altuglas® is truly *"where original ideas take shape."*

Altuglas International's **Altuglas® Medical Resins** offer a history of 30 years of outstanding performance and durability. Designed specifically for disposable medical devices, our medical resins provide excellent optical properties combined with outstanding bonding characteristics, scratch and chemical resistance, and sterilization recovery. Additionally, these resins offer ease of processing and excellent flow properties, allowing for a wide range of manufacturing processes. These and other attractive features make **Altuglas® Medical Resins** a good choice for your disposable medical device applications.



Typical Applications

Select Altuglas® Medical Resins provide medical device manufacturers with excellent isopropyl alcohol (IPA) resistance and outstanding lipid resistance. In addition, the inherent water white clarity, transparency and ease of processing of Altuglas® resins make them suitable for medical devices and diagnostic labware applications.

- Dialysis and Other Blood Therapy Systems
- IV Components and Drug Delivery Devices
  - Fluid Control Valves
  - Luers
  - Connectors
  - Spikes
  - Y-joints
  - Filter Housings
- Blood Separators
- Cardiopulmonary Housings
- Respiratory Canisters
- Yankauer Suction Tips
- In vitro Diagnostic Systems

Features and Benefits

Altuglas® Impact Modified Acrylic Resins

- Chemical Resistance
  - Outstanding resistance to lipids and drug formulations
  - Excellent resistance to isopropyl alcohol (IPA)
  - Property retention after exposure to hospital antiseptics, acids and bases
  - Low surface wetting for reduced residue build-up on the plastic surface
- Sterilization
  - Stable to gamma radiation, electron beam (E-beam), ethylene oxide (EtO)
  - Rapid recovery with excellent color stability
  - Retention of transparency and clarity
  - Retention of mechanical properties
- Durability and Processability
  - Good melt processability
  - Reduced cycle times
  - Melt flow properties allow for use in thin-wall applications and complex multi-cavity molds
  - Excellent low shear processing stability
  - Good bondability using solvent, ultrasonic, or radio frequency methods

Altuglas® UV Transmitting Acrylic Resins

- Exceptional UV Transmittance
- Excellent Transparency
- Excellent Scratch Resistance
- Excellent Processability

Product Descriptions

Altuglas® impact modified acrylic resins provide device manufacturers with transparent materials that exhibit excellent chemical resistance to IPA and lipids as well as resistance to other chemicals used in hospital settings. Acrylic impact resins are designed to provide devices with excellent optical transparency, retention of properties after sterilization, USP Class VI qualification, and multiple welding options. In addition, these resins offer 7 to 10 times more impact resistance compared to standard acrylic resins. Our proprietary impact modifier technology dramatically reduces solvent induced stress cracking by minimizing molded-in part stress. These resins process easily and offer varying degrees of modulus and impact resistance to meet specific requirements of the medical device manufacturer.

Altuglas® CR 50, Altuglas® CR 30, Altuglas® SG 10, Altuglas® SG 7 impact modified resins are designed specifically for the medical market. These resins will meet some of the toughest device requirements for sterilization, performance, regulatory compliance, and chemical resistance. They are engineered specifically for intricate and multi-compartment parts, making them excellent for applications such as dialysis cassettes, IV components, drug delivery systems, and canisters.

Product Properties Selection Guide

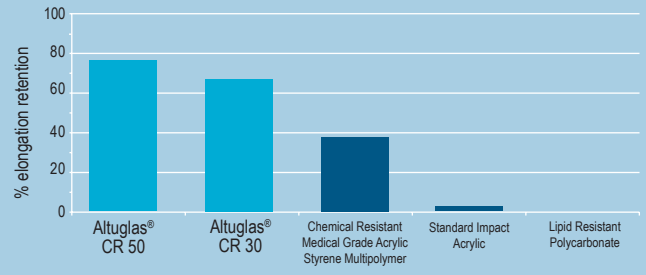
Properties	Altuglas® CR 50	Altuglas® CR 30	Altuglas® SG 10	Altuglas® SG 7	Altuglas® UVT
Chemical Resistance					
IPA	▲	●	♦	♦	■
Lipid	▲	▲	♦	♦	■
Impact Resistance	▲	▲	▲	●	■
Light Transmission	▲	▲	▲	▲	▲
UV Transmission	■	■	■	■	▲
Clarity	▲	▲	▲	▲	▲
Sterilization Resistance	▲	▲	▲	▲	■
Spiral Flow	♦	●	●	●	▲
Welding Technique					
Ultrasonic	●	●	●	●	●
Vibration	▲	▲	▲	▲	▲
Hot Plate	●	▲	▲	▲	▲

▲ Excellent ● Good ♦ Average ■ Fair

Altuglas® CR Series

Altuglas® CR Series resins are well suited for intravenous and other devices where maximum resistance to lipid emulsions, TPN solutions, or new generation oncology drugs is paramount. In support of the suggested use, Cremophor® polyethoxylated castor oil exposure was used as a test method by us to simulate the environmental stress crack resistance (ESCR) of device components to oncology drugs such as Taxol®. This and other new generation oncology drugs can aggressively attack plastics, making it challenging to design device components that are compatible and resistant to stress cracking. Altuglas® CR 50 is a premier medical resin having outstanding performance characteristics tailored to IV delivery systems that are used for highly aggressive drugs and other lipid-based formulations.

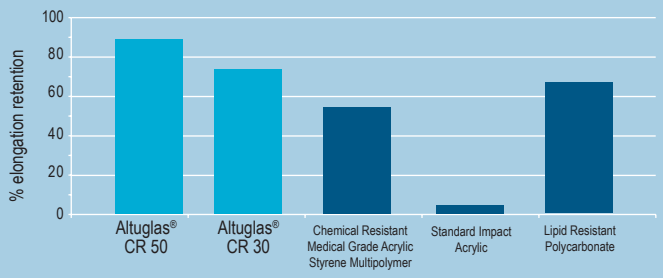
Chart 1: Resistance to Lipid* (Cremophor® RH40)



**Annealed tensile bars are exposed to chemical for 24 hrs under 1% constant strain.*

In addition, Altuglas® CR Series resistance to IPA is exceptional as compared to common commercial resins used for these applications.

Chart 2: Resistance to 70% IPA/Water*



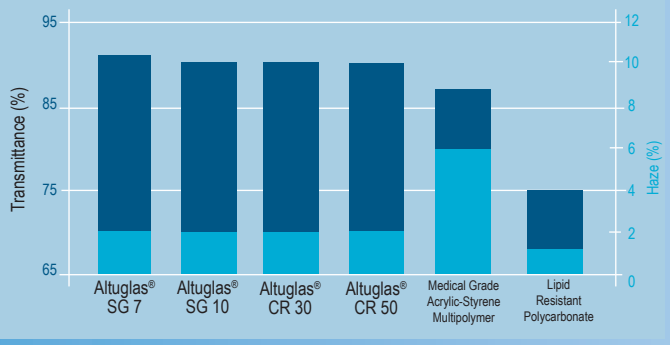
**Annealed tensile bars are exposed to chemical for 6 hrs at 0.75% constant strain.*

The increased ESCR profile of Altuglas® CR Series resins makes these excellent materials for components and devices used in drug delivery applications, such as infusion systems, stopcocks, manifolds, luers, and IV and syringe components. Since chemical resistance varies with stress level, temperature, reagent, and resin grade, testing and evaluation must be performed on actual parts and final device for each application.

Altuglas® SG Series

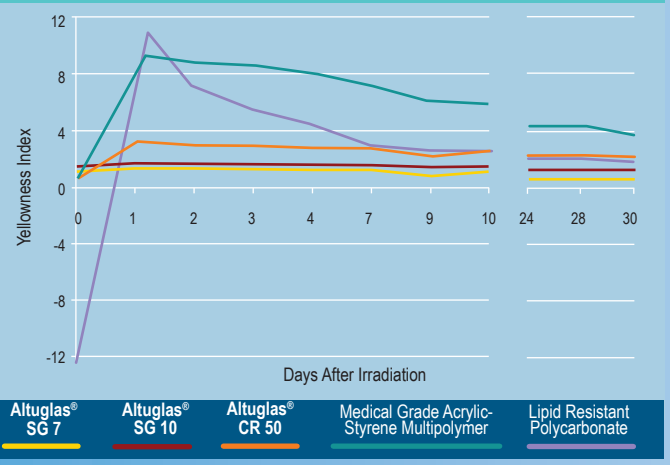
The Altuglas® SG Series resins were designed to provide excellent transmission and water white clarity for the disposable medical device market. Chart 3 demonstrates the excellence of Altuglas® SG and CR Series resins when it comes to light transmission and high clarity.

Chart 3: Transmittance and Haze of Colorless Impact Resistant Medical Resins



These altuglas® resins also exhibit excellent resistance to discoloration after high-energy sterilization methods as demonstrated in Chart 4.

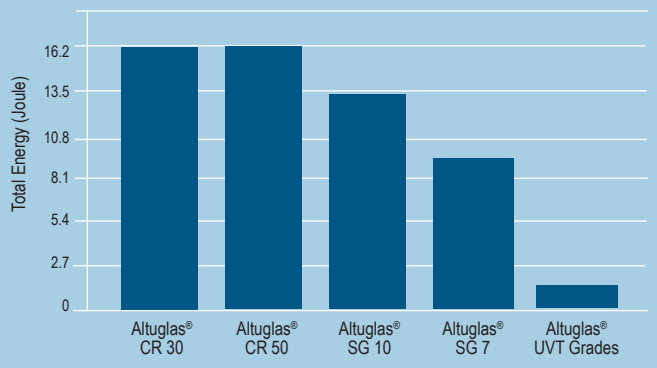
Chart 4: Color Recovery After 40 kGray Gamma Radiation



Medical devices molded from these resins start clearer and stay clearer after 40 kGrays of gamma radiation, with minimal yellowing and discoloration. This results in shorter waiting periods for device shipment and can translate into lower safety stock inventory requirements.

Chart 5 provides a comparative look at impact strength for the Altuglas® Medical Resins. These impact modified acrylic resins continue to provide impact strength, tensile strength and high modulus, even after high energy sterilization.

Chart 5: Altuglas® Impact Strength (Falling Dart) at 3.2 mm Thickness, 1.3 kg Dart, 1/4" Radius



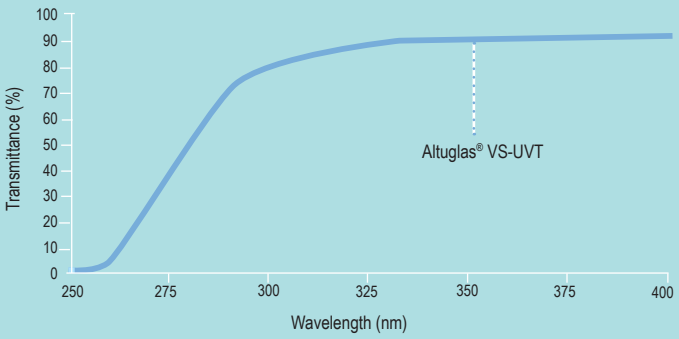
Finally, Altuglas® SG resins provide good solvent resistance. Molded medical devices using these resins have good resistance to lipids, moisture, most inorganic aqueous solutions, saline solutions, mineral oil, and limited exposure to IPA in water. Testing and evaluation must be performed on actual parts and final device for each application.

Altuglas® UVT

Altuglas® UV Transmitting Resins provide low-level fluorescence, which is easily characterized and subtracted from sample emissions. In general, acrylic resins support cell growth in tissue cultures. Additionally, applying standard surface treatment protocols will enhance this property. Finally, these resins offer very high flow values and pack out well in molded devices, providing excellent reproducibility of volumetrics.

Altuglas® VS-UVT Resin provides exceptional UV transmission and excellent transparency making it an excellent choice for in vitro diagnostics use. The UV transmission of Altuglas® VS-UVT is considerably higher than all non-acrylic materials. In addition, Altuglas® VS-UVT resin is generally tougher than UV transmitting styrenics, a common material used for this purpose. Altuglas® VS-UVT acrylic resin provides devices the outstanding optical properties needed for diagnostic accuracy.

Chart 6: Spectral Transmission of Altuglas® VS-UVT Transmitting Medical Resins @ 3.2 mm Thickness

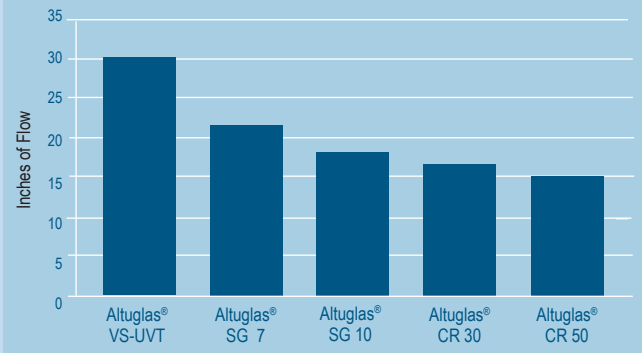


Processing and Assembly

Processability

Altuglas® Medical Resins offer excellent thermal stability with a range of melt flow rates. Spiral flow is a measurement of a material's flow characteristics and is often used as a comparative measurement of material viscosity. Altuglas® Medical Resins offer high spiral flow values and pack out well in molded devices, providing low shrinkage and excellent dimensional stability.

Chart 7: Altuglas® Spiral Flow at 240°C 2mm Channel Depth



Ultrasonic Welding

Parts molded from Altuglas® acrylic resins can be assembled by ultrasonic welding provided they are properly designed and molded using conditions that minimize stress. Specific recommendations on joint design and welding conditions should be obtained from the manufacturers of ultrasonic welding equipment.

Table 2: Weld Compatibility - Altuglas® Resins to:

Polymer	Ultrasonic	Vibration	Hot Plate
PMMA	G	E	E
ABS	G	E	E
ABS/PC	G	VG	VG
PC	G	VG	VG

Weld Rating	Excellent	Very Good	Good	Fair	Poor
Percentage of polymer* strength attainable	90 - 100%	70 - 19%	50 - 70%	25 - 50%	0 - 25%

**Tensile strength of weaker material.*

Assembly Methods

Altuglas® Medical Resins may be readily assembled to themselves or other polymers through thermal bonding (welding), or through chemical bonding with solvents or adhesives. In general, the end-use requirements for the joint will dictate which specific attachment method should be employed. Also, Altuglas® parts may be assembled by various mechanical methods, including screw fastening, riveting, or snap fits. More information on Altuglas® assembly techniques is available at www.altuglas.com/resourcecenter. Select *Technical Manual for Injection Molding.*

Table 1: Assembly Method

Joint Requirement	Thermal	Chemical
High strength	▲	●
Leak proof	▲	▲
Repeat assembly	✸	✸
Recyclability	▲	✸
Dissimilar materials	●	▲
Contamination free	▲	✸
Chemical resistance	▲	▲
Fast cycle time	▲	✸
Low capital cost	✸	●

▲ = Preferred
● = Recommended (conditions permitting)
✸ = Not recommended

Chemical Bonding

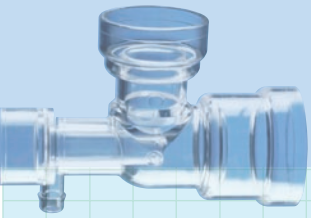
Altuglas® Medical Resins allow for easy and versatile chemical bonding. Bonding to flexible PVC tubing is best done with cyclohexanone, cyanoacrylates, tetrahydrofuran (THF), UV curable adhesives, or a 50/50 mixture of THF/MEK containing dissolved PVC chips. Altuglas® Medical Resins are compatible with plasticized PVC using DEHP (Diethylhexylphthalate) or DOP (Dioctyl Phthalate) plasticizers. As a result, Altuglas® will resist environmental stress cracking from PVC plasticizer migration often seen with other polymers.

The flexibility of Altuglas® Medical Resins also permits them to be bonded to dissimilar amorphous resins such as ABS, PC, SAN, and polyesters. Yet, for all their durability, Altuglas® acrylic devices may be easily disposed of via federally approved waste incinerators.

Table 3: Adhesive Compatibility

Polymer	Polyester	Epoxy	Cyano-acrylates	Nitrile-phenolics
Altuglas® Acrylic	▲	▲	▲	▲
ABS	▲	▲	▲	▲
Polycarbonate	▲	▲	▲	✸
Polystyrene	▲	✸	✸	✸

▲ = Preferred
● = Recommended (conditions permitting)
✸ = Not recommended



Regulatory Compliance

Upon request, Altuglas International can provide its customers with letters of compliance and authorization for device master files established through the U.S. Food and Drug Administration. For further product information on testing performed, please visit our web site at www.altuglasint.com.

Altuglas® Medical Resins Offerings: Typical Properties							
Properties	**Test Method**	**Units**	**Altuglas® CR 50**	**Altuglas® CR 30**	**Altuglas® SG 7**	**Altuglas® SG 10**	**Altuglas® VS-UVT**
Physical							
Melt Flow Rate (230°C/3.8 kg)	ISO 1133	g / 10 min	<1	<1	12.3	4.1	27.0
Specific Gravity	ISO 1183	-	1.15	1.15	1.17	1.15	1.18
Mold Shrinkage	ASTM D955	%	0.3 - 0.8	0.3 - 0.8	0.3 - 0.6	0.3 - 0.8	0.2 - 0.6
Mechanical							
Tensile Strength @ Maximum	ISO 527-2	MPa	32	33	47	37	65
Tensile Elongation @ Break	ISO 527-2	%	46	47	35	50	3
Tensile Modulus	ISO 527-2	MPa	1,550	1,650	2,450	1,860	2,900
Flexural Strength	ISO 178	MPa	46	51	86	71	97
Flexural Modulus	ISO 178	MPa	1,540	1,590	2,450	1,860	2,970
Notched Izod (23°C)	ISO 180	KJ/m^3	9	11	3.2	5	1.8
Rockwell Hardness	ASTM D785	Rockwell - Scale	67 - S	65 - S	60 - M	38 - M	84 - M
Thermal							
HDT (0.45 MPa; annealed)	ISO 75-2	°C	80	80	88	88	81
Vicat Softening Point (50°C/hr; 10N)	ISO 306B50	°C	90	90	94	93	87
Optical							
Refractive Index (nD @ 23°C)	ISO R-489	-	1.49	1.49	1.49	1.49	1.49
Luminous Transmittance (3.2 mm)	ASTM D1003	%	90	90	91	90	92
Haze (3.2 mm)	ASTM D1003	%	<2	<2	<2	<2	<2

NB : The standards quoted are not always strictly equivalent.
The values quoted are the average of results obtained under laboratory conditions and are given only as indication to enable customers to make best use of our products.

Altuglas International
89, boulevard National
F-92257 La Garenne-Colombes cedex
Tel + 33 1 78 66 23 00
Fax + 33 1 78 66 23 96

For more information, go to www.altuglasint.com

Unless Arkema otherwise expressly agrees by written contract, the Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation permanent or temporary implantable devices, and customers shall not represent to anyone else that Arkema allows, endorses or permits the use of Arkema products in such medical devices. Further, all implantable medical devices, whether permanent or temporary, carry a risk of adverse consequences. With regard to implantable medical devices, you should not rely upon the judgment of Arkema. Any decision regarding the appropriateness of a particular medical device in a particular medical application or for a specific clinical use should be based upon the judgment of your physician, medical device supplier and competent Authorities. Unless otherwise specifically stated by Arkema in writing, Arkema does not perform clinical medical studies on implantable medical devices. Arkema cannot weigh the benefits against the risks of a device and does not offer a medical judgment on the safety or efficacy of use of any Arkema product in a medical device.

Altuglas® acrylic plastic is a combustible thermoplastic. Observe fire precautions appropriate for comparable forms of wood and paper. For building uses, check code approvals. Impact resistance is a factor of thickness. Avoid exposure to heat or aromatic solvents. Clean with soap and water. Avoid abrasives.

The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, Arkema expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN. The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement.

See Safety Data Sheet for Health & Safety Considerations.
We manufacture and market PMMA resin and sheet products under the brand name Altuglas® in Asia Pacific, Europe, Africa and the Middle East, and under the brand name Plexiglas® in North and Latin America.

November, 2009