

ALTUGLAS® ALTUGLAS® LUCTOR

ACRYLIC RESINS

Medical Grades



ALTUGLAS®
BY ARKEMA

ALTUGLAS® ALTUGLAS® LUCTOR Medical Grades



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 and this tradition continues with the introduction of Altuglas® Luctor medical resins.

Altuglas International's Altuglas® medical resins offer a history of over 30 years of outstanding performance and durability, and our new Altuglas® Luctor CR13 resin adds to this legacy.

Designed specifically for disposable medical devices, Altuglas® Luctor resins provide excellent chemical resistance to ethyl and isopropyl alcohols. Just like our Altuglas® medical resins, Altuglas® Luctor CR13 has excellent scratch resistance, outstanding bonding characteristics and good optical properties.

Altuglas® and Altuglas® Luctor medical resins offer ease of processing and exceptional flow properties, allowing for a wide range of manufacturing processes. Coupled with other attractive properties and features these medical resins are a good choice for your disposable medical device applications.

Typical Applications

Altuglas® and Altuglas® Luctor medical resins provide device manufacturers with polymers having excellent resistance to lipids, plasticizers and ethyl/isopropyl alcohol (IPA). In addition, the inherent water-white clarity, transparency and ease of processing of Altuglas® resins make them suitable for diagnostic lab ware 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 apparatus
- In vitro diagnostic systems

Features and Benefits

Altuglas® and Altuglas® Luctor Impact Modified Acrylic Resins

- Chemical Resistance
 - Outstanding resistance to lipids and drug formulations
 - Exceptional resistance to ethyl and isopropyl alcohol
 - Exceptional resistance to phthalate and non-phthalate plasticizers
 - Exceptional resistance to hospital antiseptics, acids and bases
- Processability/Assembly
 - 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
- Outstanding scratch resistance
- Exceptional processability



Product Descriptions

Altuglas® and Altuglas® Luctor 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, and multiple bonding 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 moulded-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® Luctor CR13 is an impact modified acrylic resin formulated to provide exceptional resistance to ethyl and isopropyl alcohol. It has good clarity and is easily processed, allowing for use in intricate mold cavities.

The resin is also environmental friendly, having more than 25% of its carbon content derived from a bio-based source.

Altuglas® SG10 and Altuglas® SG7 impact modified resins will meet some of the toughest device requirements for processing, clarity, sterilization, performance and regulatory compliance. They are engineered specifically for intricate and multi-compartment parts, making them exceptional for applications such as dialysis cassettes, IV components, drug delivery systems, and canisters.

Product Selection Guide

Properties	Altuglas® Luctor CR13	Altuglas® SG10	Altuglas® SG7	Altuglas® VSUVT
Chemical Resistance				
IPA	E	A	A	F
Lipid	E	G	A	F
Plasticizer	E	G	G	F
Mechanical Properties				
Impact Resistance	E	G	A	F
Optics				
Light Transmission	G	E	E	E
UV Transmission	F	A	A	E
Clarity	G	E	E	E
Sterilization				
Gamma	G	E	E	F
Processing				
Spiral Flow	E	G	G	E
Welding Technique				
Ultrasonic	G	G	G	G
Vibration	E	E	E	E
Hot Plate	E	E	E	E

E = Excellent **G** = Good **A** = Average **F** = Fair

ALTUGLAS® LUCTOR

Altuglas® Luctor CR13 is a premier medical resin specifically formulated to withstand contact with IPA. It is well suited for IV delivery systems and other devices where maximum resistance to alcohols, lipid emulsions, plasticizers, TPN solutions, or new generation oncology drugs is paramount.

Chart 1 shows the results of comparative IPA exposure testing for Altuglas® Luctor CR13. The test method is designed to simulate environmental stress crack resistance (ESCR) and consists of exposing tensile bars to IPA at increasing levels of strain.

Testing is complete when the tensile bar ruptures or endures 6 hours of IPA exposure at a minimum stress of 70 MPa. Stress is calculated as the product of the polymer modulus and the maximum strain endured. The results indicate that Altuglas® Luctor CR13 matches the excellent IPA resistance exhibited by other well known medical polymers.

Chart 1: ESCR Test, Exposure to 70% IPA/H₂O for 6 Hours @ 23C

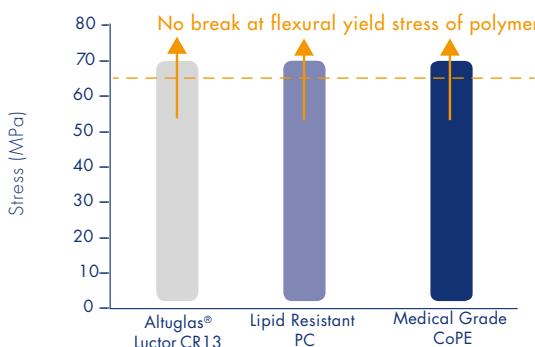
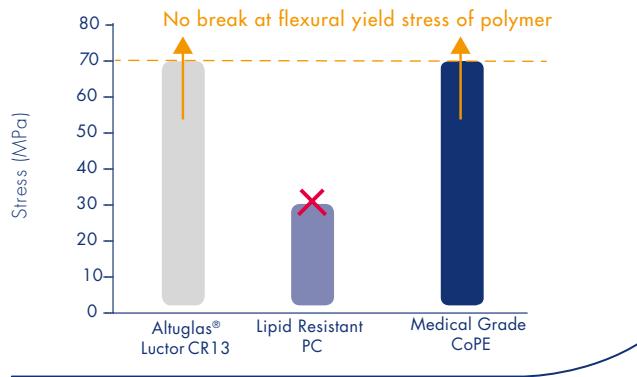




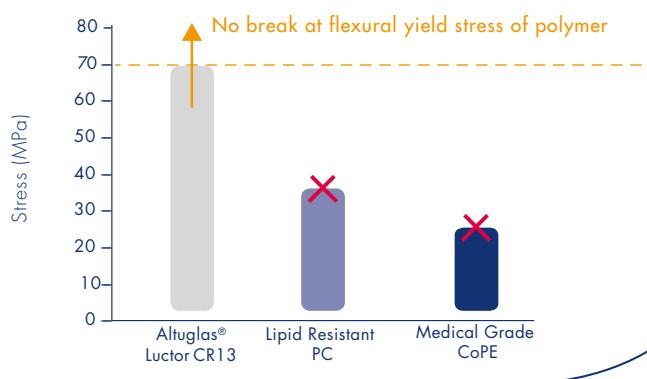
Chart 2: ESCR Test, Exposure to Cremophor® RH40 24 hrs @23C



Using the same test method, Cremophor® polyethoxylated castor oil is used as the solvent to simulate an oncology drug such as Taxol®. This and other new generation oncology drugs can aggressively attack plastics, which makes it challenging to design device components that are compatible and resistant to stress cracking. Acrylics are well known for excellent resistance to lipids and this is confirmed in Chart 2.

Medical devices often come in contact with plasticized PVC and fail due to poor ESCR. Chart 3 shows Altuglas® Luctor CR13 resists attack from phthalate and non-phthalate plasticizers.

Chart 3: ESCR Test, Exposure to Eastman™ DOP 24 hrs @23C



In addition to its exceptional performance, Altuglas® Luctor CR13 is a bio-friendly polymer with more than 25% of its carbon content derived from a renewable source.

ACRYLIC RESINS

ALTUGLAS® SG / VSUVT

The Altuglas® SG was designed to provide outstanding transmission and water-white clarity for the disposable medical device market. Chart 4 demonstrates the excellence of Altuglas® medical resins when it comes to light transmission and high clarity.

These resins also exhibit excellent resistance to discoloration after high-energy sterilization methods as demonstrated in Chart 5.

Medical devices molded from these resins start clearer and stay clearer after 40 kGray 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 6 provides a comparative look at impact strength for the Altuglas® and Altuglas® Luctor medical resins. These impact modified acrylic resins continue to provide impact strength, tensile strength and high modulus, even after high energy sterilization.

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.



Chart 4: Transmittance and Haze of Colorless Impact Medical Resins

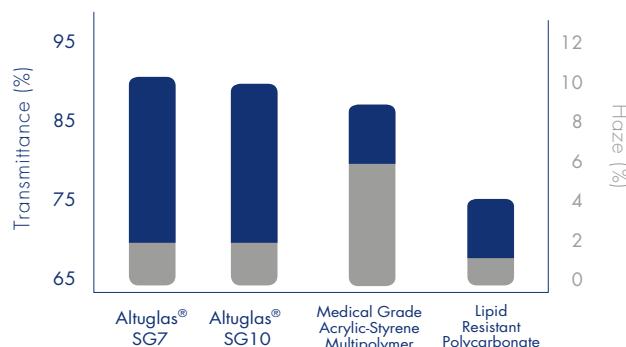
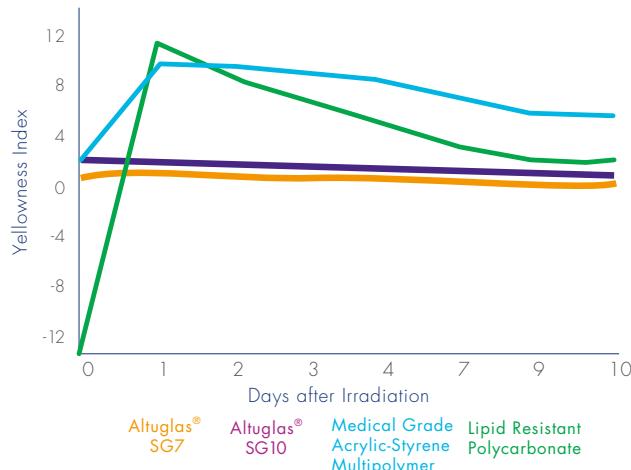
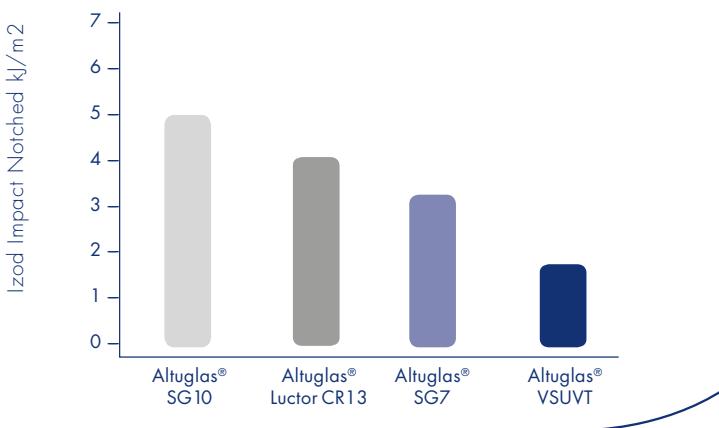


Chart 5: Resistance to 40 kGray Gamma Radiation



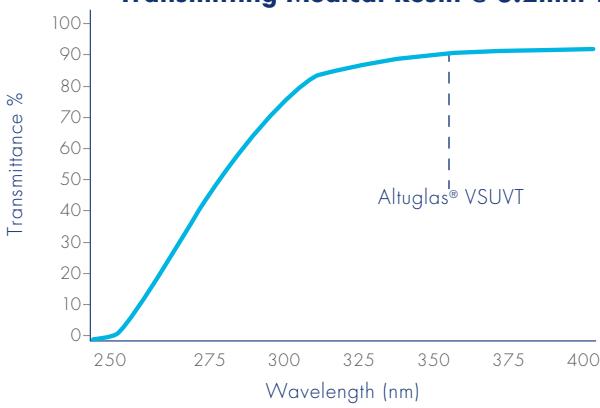


**Chart 6: Impact Strength ASTM D256
Izod Notched**



Altuglas® VSUVT resin provides exceptional UV transmission and excellent transparency, as seen in Chart 7, making it an outstanding choice for in vitro diagnostics use. The UV transmission of Altuglas® VSUVT is considerably higher than all non-acrylic materials. In addition, Altuglas® VSUVT resin is generally tougher than UV transmitting styrenics, a common material used for this purpose. Altuglas® VSUVT acrylic resin provides devices with the outstanding optical properties needed for diagnostic accuracy.

**Chart 7: Spectral Transmission of Altuglas® VSUVT
Transmitting Medical Resin @ 3.2mm Thickness**



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 enhances this property. Finally, these resins offer very high flow values and pack out well in molded devices, providing excellent reproducibility of volumetrics.



Processing and Assembly



Processability

Altuglas® and Altuglas® Luctor medical resins offer excellent thermal stability with a range of melt flow rates. Chart 8 indicates the melt flow of various polymers at low (melt flow rate) and high (spiral flow) shear rates. Altuglas® and Altuglas® Luctor medical resins offer high melt flow rates and pack out well in molded devices, providing low shrinkage and exceptional dimensional stability.

Assembly Methods

Altuglas® and Altuglas® Luctor 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® and Altuglas® Luctor parts may be assembled by various mechanical methods, including screw fastening, riveting, or snap fits. More information on assembly techniques is available at www.altuglas.com in the technical brochure titled "Injection Molding guide".

Welding

Parts molded from Altuglas® and Altuglas® Luctor acrylic resins can be assembled by 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 welding equipment.

Chart 8: Melt Flow of Altuglas® & Altuglas® Luctor CR13

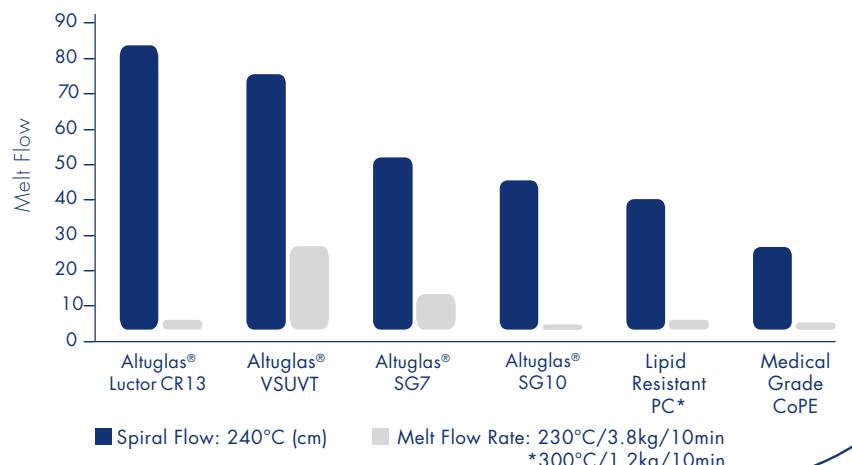


Table 1: Assembly Methods for Altuglas® & Altuglas® Luctor

Joint Requirement	Thermal	Chemical
High strength	P	R
Leak proof	P	P
Repeat assembly	NR	NR
Recyclability	P	NR
Dissimilar materials	R	P
Contaminant free	P	NR
Chemical resistance	P	P
Fast cycle time	P	NR

P = Preferred

R = Recommended (conditions permitting)

NR = Not recommended



Table 2: Weld Compatibility of Altuglas® & Altuglas® Luctor 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 Key* E=90 - 100% VG=70 - 89% G=50 - 69% F=25 - 49% P=0 - 24%

*Percentage of polymer strength attainable (tensile strength of weaker material)

Chemical Bonding

Altuglas® and Altuglas® Luctor medical resins can be successfully bonded using solvents or adhesives. Methylene chloride is the preferred solvent when joining these resins to themselves or to each other. UV curable or cyanoacrylate adhesives are recommended for bonding Altuglas® and Altuglas® Luctor medical resins to dissimilar amorphous resins such as PVC, ABS, PC, SAN, and polyesters.

When bonding Altuglas® and Altuglas® Luctor medical resins to flexible PVC tubing, a 50/50 mixture of methylene chloride or methyl ethyl ketone with cyclohexanone is recommended.

A 50/50 mixture of tetrahydrofuran with methyl ethyl ketone containing 10% dissolved PVC chips also produces good bond strength. Because Altuglas® and Altuglas® Luctor medical resins are compatible with DEHP (Diethylhexylphthalate) and alternative non-phthalate plasticized PVC, they resist environmental stress cracking often seen with other polymers caused by plasticizer migration.

Table 3: Adhesive Compatibility of Altuglas® & Altuglas® Luctor to:

Polymer	Polyester	Epoxy	Cyano-acrylates	Nitrile-phenolics
PMMA	P	P	P	P
ABS	P	P	P	P
Polycarbonate	P	P	P	NR
Polystyrene	P	NR	NR	NR

P = Preferred

R = Recommended (conditions permitting)

NR = Not recommended



Regulatory Compliance

Altuglas® SG7, SG10 and Altuglas® Luctor meet the testing requirements for USP Class VI, ISO 10993-4:2002 Hemocompatibility and ISO 10993-5:2009

Cytotoxicity. Additionally, Altuglas® Luctor was tested and meets the requirements for ISO 10993-10:2010 Skin Irritation/Sensitization. Upon request, Altuglas International will provide its customers with levels 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 website at www.altuglas.com.



Typical Properties for Altuglas® and Altuglas® Luctor Medical Grades

Conditions / Method		Measure- ment Standard	Unit	Altuglas® Luctor CR13	Altuglas® SG7	Altuglas® SG10	Altuglas® VSUVT
General Characteristics							
Density	23°C	ISO 1183	g/cm3	1.18	1.18	1.18	1.18
Mold Shrinkage	23°C	ASTM D-955	%	0.2-0.6	0.3-0.6	0.3-0.8	0.2-0.6
Mechanical properties							
Tensile Strength at Yield	23°C	ISO 527	MPa	47	48	37	66
Elongation at break	23°C	ISO 527	%	30	25	30	5
Flexural Modulus	23°C	ISO 178	MPa	2400	2200	1700	2900
Flexural Strength	23°C	ISO 178	MPa	71	83	60	97
Charpy Impact resistance (un-notched)	23°C	ISO 179-1eU	kJ/m ²	75	35	40	11
Charpy Impact resistance (notched)	23°C	ISO 179-1ea	kJ/m ²	3.2	3	5	2
Izod Impact resistance (notched)	23°C	ISO 180	kJ/m ²	4	3.2	5	1.8
Surface hardness (Rockwell scale M)	23°C	ASTM D785	HRM	42	64	37	84
Thermal properties							
Melt Index	230°C/3.kg	ISO 1133	g/10min	6.5	13	4.5	28
Vicat softening point	B50 (50 N)	ISO 306	°C	62.0	90	90	93
Vicat softening point	A50 (10 N)	ISO 306	°C	69.0	94	93	95
HDT	A (1.82 MPa)	ISO 75	°C	57.0	85	80	80
Optical properties							
Refractive index	23°C Method A	ISO 489	-	1.48	1.49	1.49	1.48
Light transmittance (3mm)	23°C	ASTM D1003	%	85	92	90	92
Haze (3mm)	23°C	ASTM D100	%	3	1.5	2	0.5
Flammability							
Fire Resistance (Class)	3.mm	UL94	Class	HB	HB	HB	HB



The products described in the brochure are Medical grades designated for Medical Device applications.

Arkema has implemented an internal Medical Device Policy regarding the use of Arkema products in medical device applications. Arkema has designated specific medical grades to be used for medical device applications. Products that have not been designated as medical grades are not authorized by Arkema for use in medical device applications.

In addition, except for limited cases as determined by the Medical Device Policy, Arkema strictly prohibits the use of any Arkema products in medical device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. Arkema will not itself perform clinical medical studies concerning the use of its products for any particular medical device application. Arkema will not engage in any type of suitability determinations for the use of its products in any medical device applications. Arkema cannot weigh the benefits against the risks of a device and does not offer a medical judgement on the safety or efficacy of use of any Arkema product in a medical device. **It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements.**

Unless Arkema otherwise expressly agrees by written contract, the Arkema trademarks and the Arkema name shall not be used in conjunction with products used in customers' medical devices applications as designated in the Medical Device Policy, 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 medical devices, whether permanent or temporary, carry a risk of adverse consequences. **It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.**

altuglas.com

About Altuglas International, a subsidiary of ARKEMA:

Altuglas International, world leader integrated in PMMA, is heavily involved in the field of engineered plastic - from MMA monomer to PMMA Acrylic glass - Altuglas International designs and manufactures highly innovative products tailored to the specific needs of its global customers. Its 1300 committed employees contribute daily to the success of its three areas of business (MMA, acrylic sheets and PMMA resins). Find out more at www.altuglasint.com.

Altuglas® and Altuglas® Luctor are combustible acrylic thermoplastics. 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.

See MSDS for Health & Safety Considerations.

We manufacture and market PMMA resin and sheet products under the brand name Plexiglas® in North and Latin America, and under the brand name Altuglas® in Asia Pacific, Europe, Africa and the Middle East. Altuglas® and Plexiglas® are registered trademarks and Luctor is a trademark of Arkema.

ALTUGLAS
INTERNATIONAL
ARKEMA GROUP

Altuglas International
89, boulevard National
F-92257 La Garenne Colombes cedex
Tel: +33 (0)1 78 66 23 00
Fax: +33 (0)1 78 66 23 96