INEOS ABS

LUSTRAN® ABS 348

ABS

Medical Grade

Description

Lustran® ABS 348 resin is an injection molding grade of ABS (Acrylonitrile butadiene styrene). It is a medium-impact, high-gloss ABS, available in natural (000000), sno-white (012002), and selected colors. The base resin used in the Lustran ABS 348 product meets FDA modified ISO 10993-1 requirements as well as U.S. Pharmacopeia 23 Class VI test requirements.

Applications

Lustran ABS 348 resin combines a good balance of physical properties, intermediate abuse resistance, and rigidity. Typical applications include components of intravenous (IV) systems, diagnostic test kits, and surgical instruments. As with any product, use of Lustran ABS 348 resin in a given application must be tested (including but not limited to field testing) in advance by the user to determine suitability.

Biocompatibility

Lustran ABS 348 resin is designated as "medical-grade" and has met the requirements of the FDA-Modified ISO 10993, Part I "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less.
Only medical-grade resins may be considered as candidates for applications requiring biocompatibility.

Regrind must not be used in medical applications requiring biocompatibility.

Manufacturer's Responsibility

It is the responsibility of the medical device, biological product, or pharmaceutical manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including Lustran ABS 348 resin, used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood, or other bodily fluids. Under no circumstances may Lustran ABS 348 resin be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may Lustran ABS 348 resin be used in any other bodily implant applications, or any applications, or any applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days, based on FDA-Modified ISO 10993, Part I "Biological Evaluation of Medical Devices" tests.

The suitability of an INEOS ABS product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single-use medical devices made from an INEOS ABS product are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

Sterilization
Parts molded from Lustran ABS 348 resin are able to be sterilized using radiation or ethylene oxide. Steam sterilization is not suitable due to the resin's insufficient heat resistance. The sterilization method and the number of sterilization cycles a part made from Lustran ABS 348 resin can withstand will vary depending upon type/grade of resin, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

Drying
Drying prior to processing is recommended in a desiccant dehumidifying hopper dryer. An inlet air dew point of -20°F (-29°C) or below is recommended to achieve a moisture content ≤0.1%. Typical drying conditions are 2 hours at 180° - 190°F (82° - 88°C). Drying for 4 hours at 160° - 170°F (71° - 77°C) is also adequate.

Processing
A reciprocating screw injection molding machine is preferred. A general-purpose screw with a 2.5:1 compression ratio is suggested. A minimum L/D ratio of 20:1 will ensure melt homogeneity.

Use minimum melt temperature with minimum barrel residence time, consistent with good part quality. To avoid excessive residence time in the barrel, volume and weight of the shot should be balanced against barrel capacity and injection stroke. A shot weight-to-machine capacity ratio of 0.5 – 0.75 is recommended. A mold temperature of 110° - 150°F (43° - 66°C) is recommended for development of maximum gloss and strength, with the hotter end of this range preferred.

Typical processing parameters are noted below. Actual processing conditions will depend on machine size, mold design, material residence time, and shot size.

Typical Injection Molding Conditions

Barrel Temperatures:	
Rear	455° – 480°F (232° – 249°C)
Middle	465° – 490°F (241° – 254°C)
Front	475° – 500°F (246° – 260°C)
Nozzle	475° – 500°F (246° – 260°C)
Melt Temperature	475° – 525°F (246° – 274°C)
Mold Temperature	110° – 150°F (43° – 66°C)
Injection Pressure	10,000 – 16,000 psi
Hold Pressure	50 – 75% of Injection Pressure
Back Pressure	0 – 25 psi
Screw Speed	Moderate
Injection Speed	High
Cushion	1/4 in max
Clamp	2 – 4 ton/in^2

Additional information on processing may be obtained by contacting an INEOS ABS technical service representative.

Regulatory Compliance Information
Some of the end uses of the product described in this bulletin must comply with applicable regulations, such as FDA, NSF, USDA, and CPSC. If you have any questions on the regulatory status of this product, contact your INEOS ABS representative or Regulatory Affairs Manager at INEOS ABS.

Health and Safety Information
Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling the INEOS ABS products mentioned in this publication. For materials mentioned which are not INEOS ABS products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be followed. Before working with any of these products, you must read and become familiar with the available information on their hazards, proper use, and handling. This cannot be overemphasized. Information is available in several forms, *e.g., material safety data sheets and product labels*. Consult your INEOS ABS representative or contact the Product Safety and Regulatory Affairs Department at INEOS ABS.

Typical Properties* for Natural Resin	ASTM Test Method (Other)	Lustran® ABS 348 Resin U.S. Conventional	Lustran® ABS 348 Resin SI Metric
General			
Specific Gravity	D 792	1.06	
Density	D 792	0.038 lb/in^3	1.06 g/cm^3
Specific Volume	D 792	26.1 in^3/lb	0.94 cm^3/lb
Mold Shrinkage	D 955	0.004 – 0.006 in/in	0.004 – 0.006 mm/mm
Instron Rheology	D 3835	210 lbs	
Melt Flow Rate at 230°C/3.8-kg Load	D 1238	5.0 g/10 min	
Melt Flow Index at 220°C/10-kg Load		14.0 g/10 min	
Mechanical			
Tensile Stress at Yield	D 638	7,000 lb/in^2	48 MPa
Tensile Modulus	D 638	380,000 lb/in^2	2.6 GPa
Flexural Stress at Yield	D 790	11,000 lb/in^2	76 MPa
Flexural Modulus	D 790	390,000 lb/in^2	2.7 GPa
Impact Strength, Notched Izod:	D 256		
0.125-in (3.2-mm) Thickness			
73°F (23°C)		4.0 ft·lb/in	214 J/m
-40°F (-40°C)		0.9 ft·lb/in	48 J/m
Rockwell Hardness, R Scale	D 785	112	
Thermal			
Deflection Temperature Under Load:	D 648		
0.5-in (12.7-mm) Thickness			
Unannealed			
264 psi (1.82 MPa)		186°F	86°C
66 psi (0.46 MPa)		199°F	93°C
Annealed			
264 psi (1.82 MPa)		204°F	96°C
66 psi (0.46 MPa)		212°F	100°C
Coefficient of Linear Thermal Expansion	D 696	4.5 E-05 in/in/°F	8.1 E-05 mm/mm/°C
Vicat Softening Temperature, Rate B	D 1525	225°F	107°C
Flammability**			
UL94 Flame Class:	(UL94)		
1.5-mm (0.059-in) Thickness		HB Rating	
3.0-mm (0.118-in) Thickness		HB Rating	

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