

LUSTRAN[®] ABS 248FC

ABS

Medical & Food Contact Grade

Description

Lustran ABS 248FC resin is a high-gloss, medium-impact grade of ABS (acrylonitrile butadiene styrene). This injection molding grade offers a good balance of physical properties and has been designed to be compliant with both medical and food contact regulations.

Applications

Lustran ABS 248FC resin is used in applications requiring rigidity and intermediate abuse resistance. As with any product, use of Lustran ABS 248FC resin in a given application must be tested (including field testing, etc.) in advance by the user to determine suitability.

Food Contact

Lustran ABS 248FC 000000 (natural) complies with FDA regulation 21 CFR 181.32 for repeated-use food-contact applications. It is also compliant with EU Directive 2002/72/EC and its amendments (2004/1/EC, 2004/19/EC, 2005/79/EC, 2008/39/EC) relating to plastic materials and articles intended to come into contact with foodstuffs.

Biocompatibility

Lustran ABS 248FC resin is designated as “medical-grade” and has met the requirements of the USP Class VI and 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.

Pre-Colored Resin

Lustran ABS 248FC can be made available (upon request) in colors that are compliant with both biocompatibility and food contact requirements.

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 248FC 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 248FC resin be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may Lustran ABS 248FC 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 248FC 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 248FC 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.

For best part quality, use the lower range of the recommended melt temperature with minimum barrel residence time. 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 (45-65°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, shot size, etc.

| Typical Injection Molding Conditions | |
|--------------------------------------|---------------------------------|
| Barrel Temperatures: | |
| Rear..... | 455°- 480°F (235°- 250°C) |
| Middle..... | 465°- 490°F (240°- 255°C) |
| Front..... | 475°- 500°F (245°- 260°C) |
| Nozzle..... | 475°- 500°F (245°- 260°C) |
| Melt Temperature..... | 475°- 510°F (245°- 265°C) |
| Mold Temperature..... | 110°- 150°F (45°- 65 °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.

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 (000000) Resin | ASTM Test Method (Other) ^a | Lustran [®] ABS 248FC Resin | |
|---|---|---|-------------------------|
| | | U.S. Conventional | 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 | 26.4 in ³ /lb | 0.94 cm ³ /g |
| Mold Shrinkage | D 955 | 0.004 - 0.006 in/in (mm/mm) | |
| Melt Flow Rate at 230°C/3.8-kg Load | D 1238 | 5 g/10 min | |
| Mechanical | | | |
| Tensile Stress at Yield | D 638 | 6,800 lb/in ² | 47 MPa |
| Tensile Modulus | D 638 | 380,000 lb/in ² | 2.6 GPa |
| Flexural Stress at Yield | D 790 | 10,700 lb/in ² | 74 MPa |
| Flexural Modulus | D 790 | 390,000 lb/in ² | 2.7 GPa |
| Impact Strength: | | | |
| 73°F (23°C) | | | |
| 0.125-in (3.2-mm) Thickness | D 256 | 4.2 ft-lbs/in | 224 J/m |
| -40°F (-40°C) | | | |
| 0.125-in (3.2-mm) Thickness | D 256 | 0.9 ft-lbs/in | 48 J/m |
| Rockwell Hardness, R Scale | D 785 | 112 | |
| Thermal | | | |
| Deflection Temperature, Unannealed: | D 648 | | |
| 0.5-in (12.7-mm) Thickness | | | |
| 264-psi (1.82-MPa) Load | | 187°F | 86°C |
| 66-psi (0.46-MPa) Load | | 200°F | 93°C |
| Deflection Temperature, Annealed: | D 648 | | |
| 0.5-in (12.7-mm) Thickness | | | |
| 264-psi (1.82-MPa) Load | | 204°F | 96°C |
| 66-psi (0.46-MPa) Load | | 212°F | 100°C |
| Deflection Temperature, Annealed, Compression Molded: | D 648 | | |
| 264-psi (1.82-MPa) Load | | 215°F | 102°C |
| Coefficient of Linear Thermal Expansion: | D 696 | 4.5 E-05 in/in/°F | 8.1 E-05 mm/mm/°C |

* These items are provided as general information only. They are approximate values and are not part of the product specifications.

Note: The information contained in this publication is current as of November 2011. Please contact INEOS ABS to determine whether this publication has been revised.

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