BioMed Black

Medical-grade matte black material for 3D printing rigid, biocompatible parts

BioMed Black Resin is a matte, opaque material for biocompatible applications requiring long-term skin contact or short-term mucosal membrane contact. This medical-grade material is suitable for applications that require high contrast for visualization, excellent definition and smooth surface quality.

Parts printed with BioMed Black Resin are compatible with common solvent disinfection and sterilization methods. BioMed Black Resin is manufactured in our ISO 13485 facility and is also USP Class VI certified which makes it suitable for pharmaceutical and drug delivery applications.

Medical devices and device components

Biocompatible molds, jigs, and fixtures

End-use parts requiring patient contact

Consumer goods

* May not be available in all regions

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof.
<table>
<thead>
<tr>
<th>MATERIAL PROPERTIES DATA</th>
<th>BioMed Black Resin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tensile Properties</strong></td>
<td><strong>Metric</strong></td>
</tr>
<tr>
<td>Ultimate Tensile Strength</td>
<td>35.71 MPa</td>
</tr>
<tr>
<td>Young’s Modulus</td>
<td>1523.74 MPa</td>
</tr>
<tr>
<td>Elongation</td>
<td>14%</td>
</tr>
<tr>
<td><strong>Flexural Properties</strong></td>
<td></td>
</tr>
<tr>
<td>Flexural Stress at 5% Strain</td>
<td>5716 MPa</td>
</tr>
<tr>
<td>Flexural Modulus</td>
<td>1668.53 MPa</td>
</tr>
<tr>
<td><strong>Hardness Properties</strong></td>
<td></td>
</tr>
<tr>
<td>Hardness Shore D</td>
<td>77 D</td>
</tr>
<tr>
<td><strong>Impact Properties</strong></td>
<td></td>
</tr>
<tr>
<td>Notched IZOD</td>
<td>24.77 J/m</td>
</tr>
<tr>
<td>Unnotched IZOD</td>
<td>348.03 J/m</td>
</tr>
<tr>
<td><strong>Thermal Properties</strong></td>
<td></td>
</tr>
<tr>
<td>Heat Deflection Temp. @ 1.8 MPa</td>
<td>49.4 °C</td>
</tr>
<tr>
<td>Heat Deflection Temp. @ 0.45 MPa</td>
<td>67.9 °C</td>
</tr>
<tr>
<td>Coefficient of Thermal Expansion</td>
<td>106.9 μm/m/°C</td>
</tr>
<tr>
<td><strong>Other Properties</strong></td>
<td></td>
</tr>
<tr>
<td>Water Absorption</td>
<td>0.44 wt%</td>
</tr>
</tbody>
</table>

**Sterilization Compatibility**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-beam</td>
<td>35 kGy E-beam radiation</td>
</tr>
<tr>
<td>Ethylene Oxide</td>
<td>100% Ethylene oxide at 55 °C for 180 minutes</td>
</tr>
<tr>
<td>Gamma</td>
<td>29.4 - 31.2 kGy gamma radiation</td>
</tr>
<tr>
<td>Steam Sterilization</td>
<td>Autoclave at 134°C for 20 minutes, Autoclave at 121°C for 30 minutes</td>
</tr>
</tbody>
</table>

**Disinfection Compatibility**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Disinfection</td>
<td>70% Isopropyl Alcohol for 5 minutes</td>
</tr>
</tbody>
</table>

Samples printed with BioMed Black Resin have been evaluated in accordance with the following biocompatibility endpoints:

ISO Standard | Description
--- | ---
ISO 10993-5:2009 | Not cytotoxic
ISO 10993-10:2010/(R)2014 | Not an irritant
ISO 10993-10:2010/(R)2014 | Not a sensitizer

The product was developed and is in compliance with the following ISO Standards:

ISO Standard | Description
--- | ---
EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices

1 Material properties may vary based on part geometry, print orientation, print settings, temperature, and disinfection or sterilization methods used.
2 Data were measured on post-cured samples printed on a Form 3B with 100um BioMed Black Resin settings, washed in a Form Wash for 5 minutes in 99% Isopropyl Alcohol, and post-cured at 70°C, 60 minutes in a Form Cure.
3 BioMed Black Resin was tested at NAMSA World Headquarters, OH, USA.
<table>
<thead>
<tr>
<th>Solvent</th>
<th>24 hr weight gain, %</th>
<th>Solvent</th>
<th>24 hr weight gain, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic Acid 5%</td>
<td>0.3</td>
<td>Mineral oil, heavy</td>
<td>0.2</td>
</tr>
<tr>
<td>Acetone</td>
<td>3.1</td>
<td>Mineral oil, light</td>
<td>0.2</td>
</tr>
<tr>
<td>Bleach ~5% NaOCl</td>
<td>0.2</td>
<td>Salt Water (3.5% NaCl)</td>
<td>0.3</td>
</tr>
<tr>
<td>Butyl Acetate</td>
<td>0.4</td>
<td>Skydrol 5</td>
<td>0.6</td>
</tr>
<tr>
<td>Diesel Fuel</td>
<td>0.1</td>
<td>Sodium hydroxide solution (0.025% pH = 10)</td>
<td>0.3</td>
</tr>
<tr>
<td>Diethyl glycol monomethyl ether</td>
<td>1.0</td>
<td>Strong Acid (HCl Conc)</td>
<td>0.2</td>
</tr>
<tr>
<td>Hydraulic Oil</td>
<td>0.2</td>
<td>TPM</td>
<td>0.6</td>
</tr>
<tr>
<td>Hydrogen peroxide (3%)</td>
<td>0.3</td>
<td>Water</td>
<td>0.3</td>
</tr>
<tr>
<td>Isooctane</td>
<td>&lt; 0.1</td>
<td>Xylene</td>
<td>0.3</td>
</tr>
<tr>
<td>Isopropyl Alcohol</td>
<td>0.2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>