

Reference Documentation

FDM Material Biocompatibility and Sterilizability

The tables below contain links to current information supporting biocompatibility and sterilizability of ABS-M30i™, PC-ISO™ and ULTEM™ 1010 resin FDM® materials.

Note: Clicking on the hyperlinks in the “Document Title” column will automatically download the PDF document from the stratasys.com website.

ABS-M30i		
Category	Document Title	Source
Sterilizability	Certificate of Material Sterilizability	Nelson Labs – 6/11/19
Toxicity, Genotoxicity, Carcinogenicity	Toxicological Risk Assessment	Nelson Labs – 4/19/19
Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Hemocompatibility, Acute/Subacute/Sub-Chronic/Chronic Toxicity, Genotoxicity, and Carcinogenicity	Certificate of Material Biocompatibility NOTE: this document identifies biocompatibility with material printed on the F370 printer. However this material/printer combination has not been put into production at this time.	Nelson Labs – 6/30/19

PC-ISO		
Category	Document Title	Source
Sterilizability (T-translucent)	Certificate of Material Sterilizability	Nelson Labs – 6/11/19
Sterilizability (white)	Certificate of Material Sterilizability	Nelson Labs – 6/11/19
Summary of Chemical Analysis (translucent)	Extractable/Leachable Chemical Analysis: Summary of Results	Nelson Labs – 1/10/19
Summary of Chemical Analysis (white)	Extractable/Leachable Chemical Analysis: Summary of Results	Nelson Labs – 1/10/19
Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Hemocompatibility, Acute/Subacute/Sub-Chronic/Chronic Toxicity, Genotoxicity, and Carcinogenicity (PC-ISO-T)	Certificate of Material Biocompatibility	Nelson Labs – 6/11/19
Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Hemocompatibility, Acute/Subacute/Sub-Chronic/Chronic Toxicity, Genotoxicity, and Carcinogenicity (PC-ISO white)	Certificate of Material Biocompatibility	Nelson Labs – 6/11/19

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ULTEM 1010		
Category	Document Title	Source
Sterilizability	Declaration of Compliance with EN ISO 10993-1	Emergo – 10/10/18
Pyrogenicity	ISO Materials Mediated Pyrogen (GLP)	Nelson Labs – 1/28/19
USP Plastics Class VI 50 °C	Classification of Plastics Plastic Class VI – 50 °C	eurofins – 3/15/18
Mutagenicity	Reverse Mutation Assay Using Bacteria With Extracts (Polar and Non-Polar) of ULTEM 1010	eurofins – 3/15/18
Skin Sensitization (Polar Extract)	Skin Sensitization (Guinea Pig Maximisation Test) With a Polar Extract of ULTEM 1010	eurofins – 3/15/18
Skin Sensitization (Nonpolar Extract)	Skin Sensitization (Guinea Pig Maximisation Test) With a Nonpolar Extract of ULTEM 1010	eurofins – 3/15/18
Cytotoxicity	Cytotoxicity Growth Inhibition Test in L929 Mouse Fibroblasts (Elution Test) With Different Processed ULTEM 1010	UL MDT – 9/5/17
Cytotoxicity, Irritation, Delayed Type Hypersensitivity, Pyrogenicity, Acute Toxicity, Chemical Characterization, Allowables for Leachable Substances	Declaration of Compliance with EN ISO 10993-1 Overall Biological Risk Assessment for the 3D Printing Material ULTEM 1010	Emergo – 10/10/18
Leachable Compounds	Investigation of Extractable Organic Substances (GC/MS Fingerprint) and Inorganic Ions (ICP-OES Investigation) After Liquid Extraction of Different Processed ULTEM 1010	UL MDT – 10/11/17
Genotoxicity	Declaration of Compliance with EN ISO 10993-1 Overall Biological Risk Assessment for the 3D Printing Material ULTEM 1010	Emergo – 10/10/18
IR Spectroscopy	Infrared Spectroscopy Final Report	Nelson Labs – 7/15/19
Differential Scanning Calorimetry	Differential Scanning Calorimetry Final Report	Nelson Labs – 7/18/19
Manufacturer Biocompatibility Report	Biocompatibility Statement for ULTEM 1010 Resin HU1010	SABIC – 10/30/14
Smoke Density	Test Report – Smoke Density Testing	element – 11/25/14

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