

# ISO 10993 and US FDA Intact Skin Surface Devices Statement



## HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D High Reusability CB PA 12

**Original HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D HR CB PA 12 material (“HP Agents & CB PA 12 Material”) have met the US Food and Drug Administration’s (“FDA”) guidance and ISO 10993-1 standard for Intact Skin Surface Devices.** This conclusion is based on the following guidelines and tests conducted at a certified third-party laboratory:

- 1. Cytotoxicity** – ISO 10993-5, Biological evaluation of medical devices – part 5: Tests for in vitro cytotoxicity.
- 2. Sensitization and irritation** – ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- 3. Acute systemic toxicity** – ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.
- 4. Pyrogenicity** – USP, General Chapter <151>, Pyrogen test. Recommended in ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.

The results from the above-referenced testing are representative of parts produced on the HP Jet Fusion 540 3D printers over the range of available printmodes with HP Agents & CB PA12 Material. The only post processing that the parts underwent were sand blasting, a soak in isopropanol for 30 minutes, and a rinse in deionized water. Based on these results, HP expects that similar parts made from the HP Agents & CB PA 12 Material under recommended operating conditions as per the site preparation guide will be suitable for applications described in FDA’s and ISO 10993’s guidance for Intact Skin Surface Devices.

It is the responsibility of each customer to determine that its use of HP Agents & CB PA 12 Material is safe and technically suitable to the customer’s intended applications and consistent with the relevant regulatory requirements (including FDA requirements) applicable to the customer’s final product. Customers should conduct their own testing to ensure that this is the case. Results may vary if the testing is performed under different conditions than those existing at testing time and/or those required testing conditions that applied for the purposes of the biocompatibility tests referenced above. Because of possible changes in the relevant industry standards, FDA guidance, and other legal or regulatory requirements, as well as possible changes in HP Agents & CB PA 12 Materials, HP cannot guarantee that the status of HP Agents & CB PA 12 Material will remain unchanged or that it will qualify for or comply with FDA’s and/or ISO 10993’s guidance for Intact Skin Surface Devices in any particular use.

For additional information about HP 3D400 Fusing, Detailing, and Bright Fusing Agents and HP 3D HR CB PA 12, please contact our HP 3D Printing Materials team at [3dmaterials@hp.com](mailto:3dmaterials@hp.com).



White paper

# HP 3D HR CB PA 12 for HP Jet Fusion 500 Series 3D Printers

**Mechanical Properties**



## Introduction

At HP, we are committed to providing part designers and part manufacturers with the technical information and resources needed to enable them to unlock the full potential of 3D printing and prepare them for the future era of digital manufacturing.

The aim of this white paper is to illustrate the mechanical properties of HP 3D Printing materials that can be achieved with HP Jet Fusion 500 Series 3D Printers.

In this white paper, you will find:

- Key mechanical properties for HP 3D High Reusability (HR)<sup>1</sup> Color Boost (CB) PA 12,
- A detailed explanation of the test conditions under which these values were obtained, and
- Additional information on the mechanical properties of thermoplastic materials, and a glossary of key terms used.

## Material properties for HP 3D HR CB PA 12

### Test job for white parts

The baseline mechanical properties for HP 3D HR CB PA 12 with the HP Jet Fusion 500 Series 3D Printers were characterized using a test job *Job2643\_Mechanical\_Half\_Datasheet\_R1\_White.ssp* (Figure 1) to evaluate white part properties and material performance.

The print volume was packed at 6.3% and had a total of 212 white diagnostic parts that were distributed throughout the printable volume.

The configuration of this job is shown in Figure 1.

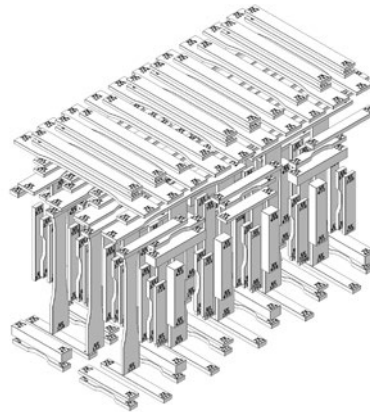


Figure 1. *Job2643\_Mechanical\_Half\_Datasheet\_R1\_White.ssp* mechanical properties characterization job

Test job description	<i>Job2643_Mechanical_Half_Datasheet_R1_White.ssp</i>
Total parts	212
Time to print	8 hours
Time to cool (Auto Cool & Reclaim)	7 hours
Packing density	6.3%

Table 1. General description of the test job

1. HP Jet Fusion 3D Printing Solutions using HP 3D High Reusability PA 12 provide up to 80% powder reusability ratio, producing functional parts batch after batch. For testing, material is aged in real printing conditions and powder is tracked by generations (worst case for reusability). Parts are then made from each generation and tested for mechanical properties and accuracy.

Standard tensile sample parts Type I, Type V, and Impact Izod (3.2 mm) were selected to measure the different metrics in three different orientations.

	Number of samples		
	X	Y	Z
Tensile Type I	20	20	42
Tensile Type V	15	15	30
Impact Izod (3.2 mm)	20	20	30

Table 2. Number of samples used in the test job

### Test job for colored parts

The baseline mechanical properties for HP 3D HR CB PA 12 with the HP Jet Fusion 580 Color 3D Printer have been characterized using a standard job *Job2717\_Mechanical\_Half\_Datasheet\_R1\_Color.ssp* (Figure 2) to evaluate colored part properties and material performance.

The printable volume was packed at 6.3% and had a total of 212 colored diagnostic parts that were distributed throughout the printable volume. The configuration of this job can be seen in Figure 2.

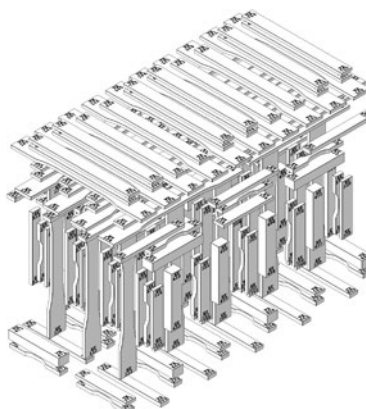


Figure 2. *Job2717\_Mechanical\_Half\_Datasheet\_R1\_Color.ssp* mechanical properties characterization job

Test job description	Job 2717_Mechanical_Half_Datasheet_R1_Color.ssp
Total parts	212
Time to print	8 hours
Time to cool (Auto Cool & Reclaim)	7 hours
Packing density	6.3%

Table 3. General description of the test job

Standard tensile sample parts Type I, Type V, and Impact Izod (3.2 mm) were selected to measure the different metrics in three different orientations.

	Number of samples		
	X	Y	Z
Tensile Type I	20	20	42
Tensile Type V	15	15	30
Impact Izod 3.2 mm	20	20	30

Table 4. Number of samples used in the test job

## Characterization test results

### Results for white parts

The mechanical property values for white parts indicated in Table 5 have been characterized using the test job for white parts mentioned previously in the HP Jet Fusion 580 Color 3D Printer with the Mono Balanced print profile, with Type I tensile specimens following the ASTM D638 standard.

HP 3D HR CB PA 12 white parts printed on the HP Jet Fusion 540 3D Printer with the CB PA 12 Balanced print profile will produce similar results.

HP 3D HR CB PA 12 <sup>i,ii,iii</sup>	Average (XY)	Average Z	Test Method
Tensile strength (MPa) <sup>iv</sup>	49	49	ASTM D638
Tensile modulus (MPa) <sup>iv</sup>	1800	1900	ASTM D638
Elongation at yield (%)	11	9	ASTM D638
Elongation at break (%)	17	11	ASTM D638
Impact strength (kJ/m <sup>2</sup> ) <sup>v</sup>	3.2	2.7	ASTM D256
Density (g/cm <sup>3</sup> )	1.01		ASTM D792

*i. Based on internal testing and measured using the Job2643\_Mechanical\_Half\_Datasheet\_R1\_White.ssp. Results may vary with other jobs and geometries.*

*ii. Using HP 3D HR CB PA 12 material, 20% refresh ratio, Balanced print profile, natural cooling and measured after bead-blasting with glass beads at 5-6 bars.*

*iii. Following all HP-recommended printer setup and adjustment processes.*

*iv. Tensile strength typical variation (95% of parts) falls within the 46-53 MPa range, while tensile modulus values remain within the 1650 to 2300 MPa range.*

*v. Using the Izod test method A with notched @ 3.2 mm specimen according to the ASTM D256 standard.*

Table 5. Results for white parts in HP 3D HR CB PA 12 printed with Mono Balanced print profile

## Results for colored parts

The mechanical property values for colored parts indicated in Table 6 have been obtained from the HP Jet Fusion 580 Color 3D Printer, for HP 3D HR CB PA 12 with the Color Balanced print profile, using Type I tensile specimens following the ASTM D638 standard.

Average mechanical properties may vary by color and are indicated by the ranges below. Dark colors such as black tend to fall in the low end of these ranges.

HP 3D HR CB PA 12 <sup>iii</sup>	Average (XY)	Average (Z)	Test Method
Tensile strength (MPa)	36-44	34-45	ASTM D638
Tensile modulus (MPa)	1300-1600	1400-1700	ASTM D638
Elongation at yield (%)	10-12	5-10	ASTM D638
Elongation at break (%)	10-17	5-12	ASTM D638
Impact strength (kJ/m <sup>2</sup> ) <sup>iv</sup>	3.6-3.9	2.5-3.0	ASTM D256
Density (g/cm <sup>3</sup> )	1.01		ASTM D792

*i. Based on internal testing and measured using the Job2717\_Mechanical\_Half\_Datasheet\_R1\_Color.ssp. Results may vary with other jobs and geometries.*

*ii. Using HP 3D HR CB PA 12 material, 20% refresh ratio, Balanced print profile, natural cooling, and measured after bead-blasting with glass beads at 5-6 bars.*

*iii. Following all HP-recommended printer setup and adjustment processes.*

*iv. Using the Izod test method A with notched @ 3.2 mm specimen according to the ASTM D256 standard.*

Table 6. Results for colored parts in HP 3D HR CB PA 12 printed with Color Balanced print profile

## Appendix 1: Choosing the right material for mechanical requirements

One of the most critical aspects to understand before choosing a material is the stresses the part will experience in its regular operation mode. The chosen material must meet the application's requirements in terms of behavior under stress and provide a suitable yield point in order not to impact the part's functionality. Loads, boundary conditions, and design space for the part are usually given parameters, which cannot be modified. In some other cases where the loads may vary due to a dynamic situation, other factors and calculations should be considered to ensure, for instance, that the part withstand fatigue.

Ideally, designers should choose the material based on the application's specific requirements. However, performing the final selection is not easy, as often not all of the requirements for the application are known and, even if they are, there may not be a clear correlation between these final application requirements and the generic material properties (characterized by the standard procedures) or the variations the materials may have depending on the environment and conditions in which they operate. To simplify this choice, the commonly used process for material selection involves three steps:

STEP 1: Select a material with generic properties according to key attributes. In thermoplastics, the most commonly used properties are tensile strength, tensile modulus, and elongation, (but others may also be considered).

- Tensile strength measures the resistance of the material to breaking under tension.
- Tensile modulus measures the rigidity or resistance to elastic deformation.
- Elongation measures the deformation (elastic or plastic) that a part undergoes given a certain strain.

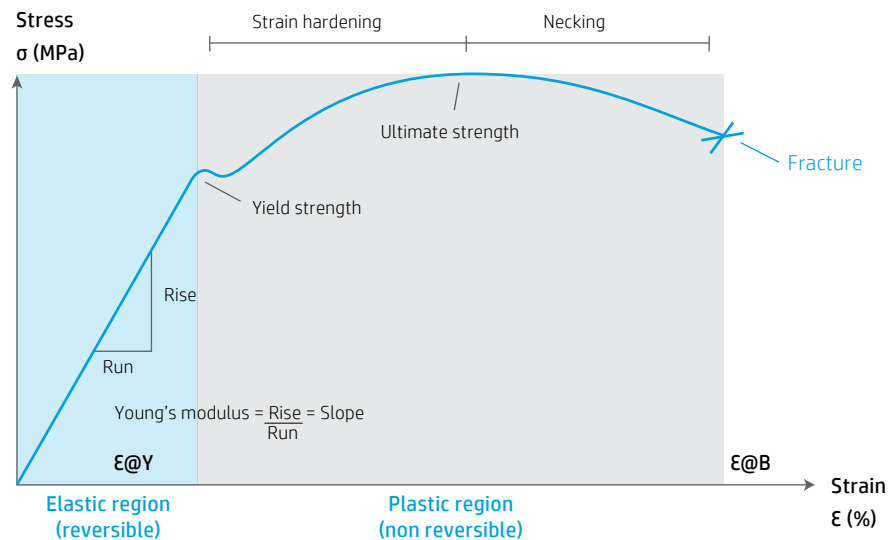


Figure 3. A typical stress-strain curve for a ductile material

These properties and the relative behavior of polymers compared to other materials are shown in Figure 4.

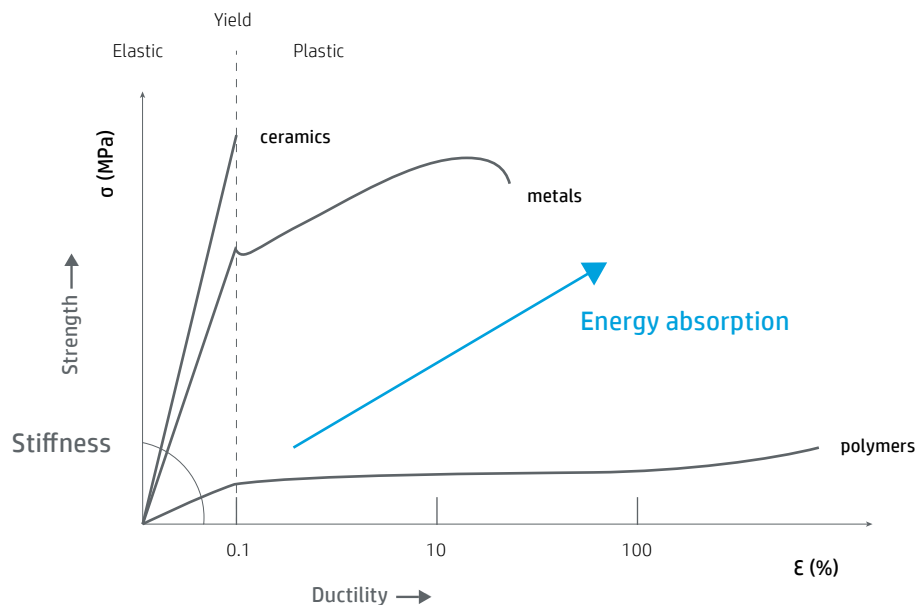


Figure 4. Comparison of polymer, metal, and ceramic materials

STEP 2: Once a material has been selected, the design of the part needs to be performed in line with HP Multi Jet Fusion design guidelines, allowing enough of a design margin (two or three times, depending on the property) to accommodate for all possible variations in the part itself or in the application-specific conditions.

STEP 3: Even after the design has been performed according to these principles, it is highly advisable to conduct a full application-specific qualification to ensure the precision of the design, obtain validation data that represent the application's end-to-end performance, and characterize its variation over time or according to other production and application variation factors.



## Appendix 2: Key terms

- **Tensile strength** or Ultimate Tensile Strength (UTS) is typically measured in MPa or N/mm<sup>2</sup>. It is the capacity of a material to withstand tension loads. Tensile strength is measured by the maximum stress that a material can withstand while being pulled before breaking.
- **Tensile modulus** or Modulus of Elasticity or Young's Modulus or E is typically measured in MPa or N/mm<sup>2</sup>. It is a mechanical property that measures the stiffness of a solid material. It defines the relationship between stress and strain in a material in the linear elasticity regime. Since thermoplastics have a very short linear elasticity zone, it is calculated as the slope of the stress-strain curve very close to zero. Tensile modulus is required as an input for mechanical FEA simulations.
- **Elongation** measures the deformation that a part undergoes given a certain stress, for thermoplastics it is typically expressed as a percentage (%) of the deformed amount versus the original part length.
  - **Elongation at yield** in thermoplastics is the deformation corresponding to the tensile strength point, so where the stress-strain curve has its maximum.
  - **Elongation at break** is the deformation corresponding to the fracture point of the part.
- **Impact strength** measures the impact resistance of a material or the amount of energy absorbed by a material during fracture which has to do with its toughness. The units are typically kJ/m<sup>2</sup> so energy per unit area. There are two standard methods to measure it: the Izod and the Charpy. Notched and unnotched specimens are used on the specific pendulum testers to determine the impact strength and the notch sensitivity.
- **Stress** is the force density (quotient of internal force and effective area prevailing in every area element). There are two types of stresses depending on their direction to the cross-sectional plane studied: normal stress and shear stress.
- **Deformation** refers to any stress on a solid body that generates strain. A distinction is made between elastic and plastic deformation. Elastic deformations disappear once the imposed external load has been removed. Plastic deformations occur when the inner stresses exceed a certain limit that is intrinsic to the material. In this case deformations will remain after removal of the external load. Hence, plastic deformation is permanent and non-reversible.

