

HP 3D HR PA11

Summary of Regulatory Compliance and Environmental Attributes



Introduction

The purpose of this document is to describe the regulatory and environmental attributes of HP Inc.'s ("HP") HP 3D HR PA11. Safety Data Sheets ("SDSs") such as those required by the Hazard Communication Standard of the U.S. Occupational Safety and Health Administration ("OSHA") and similar requirements in other countries can be found at www.hp.com/go/ecodata.

HP 3D HR PA11 is a polyamide powder designed by HP and our partner to meet worldwide regulatory requirements and to address a broad range of health and environmental considerations throughout the entire life cycle of a print from production to disposal.

Please refer to the HP 3D600 700 710 Agents statement for similar information on the agents.

Regulatory Summary

Chemical Inventory Status

The following countries have chemical inventory requirements and HP 3D HR PA11 can be imported without restriction:

- Australia (AICS)
- Canada (DSL, NDSL)
- Providence of Ontario
- China (IECSC)
- Japan (ISHL)
- Japan (CSCL/ENCS)
- Korea (KECI, K-REACH)
- New Zealand (NZIoC)
- Philippines (PICCS)
- Switzerland (ChemO)
- Taiwan (ECSI)
- United States (TSCA)

For EU REACH, HP and/or our partner have completed all necessary pre-registrations/registrations to import HP 3D HR PA11.

Regulated Materials

HP 3D HR PA11 DOES NOT contain the following regulated materials:

- Arsenic, antimony, soluble barium, cadmium, chromium, cobalt, mercury, lead, nickel, copper, and selenium as intentionally added ingredients



- Restricted azo colorants¹
- Substances currently regulated under Annex XIV of EU REACH (authorisations) or substances currently restricted under Annex XVII of EU REACH (restrictions)
- Halogenated organics

Health and Environmental Performance

Human and Ecological Health

HP 3D HR PA11 is considered non-hazardous according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS, as implemented by the EU Classification, Labeling and Packing Regulation No 1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations.

HP 3D HR PA11 does not contain intentionally added components in the following categories:

- Carcinogens, mutagens, or reproductive toxins (CMRs);
- California Proposition 65 listed chemicals at concentrations requiring labeling;
- Substances identified as endocrine disruptors;
- Substances considered very toxic or toxic;
- Substances classified as respiratory sensitizers;
- Substances identified as "very high concern" (SVHC) according to EU REACH criteria; and
- Substances identified as "very persistent and/or very bioaccumulative" (vPvB) according to EU REACH criteria.

Transportation

HP 3D HR PA11 is Not Readily Combustible Solid of Division 4.1, Not Classified as a Flammable Solid², and does not require special handling, storage, or transportation-related conditions. This formulation is not classified as Dangerous Goods in accordance with international modes of transport (IATA, IMDG, U.S. DOT, and/or ADR) and does not contain listed marine pollutants.

¹ EU Directive 2002/61/EC, additionally referenced as Regulation (EC) No 1907/2006: REACH, Annex XVI (article 67), restricts the use of azo colorants that break down to aromatic amines known to cause cancer.

² HP 3D HR PA11 tested per the Flammability Regulation (EC) No. 440/2008 – Test A10 Flammability (Solids) UN Recommendations on the Transport of Dangerous good, Manual of Tests and Criteria – For Solids: Test N1, sub-section 33.2.1.4.



Waste Profile Datasheet

HP is providing the information in this section voluntarily as a service to assist customers in determining appropriate disposal methods for this product at the end of life.

Flammability

Not Readily Combustible Solid of Division 4.1, Not Classified as a Flammable Solid per Flammability Regulation (EC) No. 440/2008 – Test A10 Flammability (Solids) UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria – For Solids: Test N1, sub-section 33.2.1.4.

Organics (US EPA Method SW8260B and SW8270C)

None of the substances and compounds with a regulatory threshold as set by California 22 CCR Section Table 1 were detected above the regulatory threshold.

Metals Content – (US EPA Method SW6010B and SW7471A)

Antimony	<0.2 mg/kg
Arsenic	<0.25 mg/kg
Barium	<0.07 mg/kg
Beryllium	<0.0800 mg/kg
Cadmium	<0.0550 mg/kg
Chromium	<0.0500 mg/kg
Cobalt	<0.055 mg/kg
Copper	<0.650 mg/kg
Lead	<0.14 mg/kg
Mercury	<0.2 mg/kg
Molybdenum	<0.12 mg/kg
Nickel	<0.050 mg/kg
Selenium	<0.42 mg/kg
Silver	<0.37 mg/kg
Thallium	<0.49 mg/kg
Vanadium	<0.18 mg/kg
Zinc	<0.25 mg/kg

Aquatic Toxicity

- LC50 for fish is >750 mg/L per DOHS (Title 22) Hazardous Waste Bioassay using Fathead Minnow
- The powder does not carry an aquatic toxicity classification according to EC Regulation No. 1272/2008.

Restriction of Hazardous Substances (RoHS)

Parts printed on an HP 3D printer using HP 3D600/700 Agents and HP 3D HR PA 11 have been tested for RoHS (Directive 2011/65/EU as amended by Directive EU 2015/863) restricted substances following IEC 62321 standards. RoHS heavy metals (cadmium, lead, and mercury), bromine, and chlorine were not detected by XRF. The result for soluble chromium was <2.0 ppm by ASTM F963-17, section 8.3.5. No regulated phthalates were detected above 50 ppm.



Polycyclic Aromatic Hydrocarbons (PAHs)

Parts printed on an HP 3D printer using HP 3D600/700 Agents and HP 3D HR PA 11 were tested for PAHs. No PAHs stated in table 1 were detected above the detection limit of 1 ppb using GC/MS.

Table 1. PAHs Tested

Naphthalene
Acenaphthylene
Acenaphthene
Fluorene
Phenanthrene
Anthracene
Fluoranthrene
Pyrene
Benzo[c]phenanthrene
Benzo[c]anthracene
Chrysene
Benzo[b]fluoranthene
Benzo[k]fluoranthene
Benzo[j]fluoranthene
Benzo[a]pyrene
Benzo[e]pyrene
3-Methylcholanthrene
Dibenzo[a,h]anthracene
Indeno[1,2,3-cd]pyrene
Benzo[g,h,i]perylene

Phthalates

Parts printed on an HP 3D printer using HP 3D600/700 Agents and HP 3D HR PA 11 were tested for regulated phthalates listed in table 2 and the results were <50 ppm.



Table 2. Phthalates Tested

Di-butyl phthalate (DBP)
Butyl benzyl phthalate (BBP)
Di(2-ethylhexyl) phthalate (DEHP)
Di(n-octyl) phthalate (DnOP)
Di(iso-nonyl) phthalate (DINP)
Di-(is-decyl) phthalate (DIDP)
Di-n-hexyl phthalate (DnHP)

Bisphenol A

Parts printed on an HP 3D printer using HP 3D600/700 Agents and HP 3D HR PA 11 were tested for bisphenol A and was below the detection level of 0.1 mg/kg in printed parts.

Recyclability

HP 3D HR PA11 powder is supplied in containers of which approximately 80% of the weight of the used empty container is a recyclable cardboard. For disassembly instructions of the container please visit the following page: https://h30248.www3.hp.com/recycle/supplies/pdf/powder_container_recycling_instructions.pdf.

HP Design for Environment (DfE) Program

In 1992, HP adopted a pioneering company-wide Design for the Environment program that considers environmental impact in the design of every product and solution, from the smallest ink cartridge to entire data centers.

For more information about HP's social and environmental responsibility programs, see www.hp.com/livingprogress.

Food Contact

Currently, no HP 3D materials are designed or approved for direct or indirect food contact applications and accordingly they should not be used for food applications or direct and indirect food contact applications.



USP Class I-VI and FDA Intact Skin Surface Devices Statement

HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11

Original HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 material (“HP Agents & PA11 Material”) have met the requirements of USP Class I-VI and the US Food and Drug Administration’s (FDA) guidance 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. Muscle implantation – USP, General Chapter <88>, Biological Reactivity Tests, In vivo – Muscle implantation
5. 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 3D 4200/4210 printers over the range of available printmodes with HP Agents & PA11 Material. HP 3D HR PA11 fresh and recycled (70% recycled/30% fresh) material was used for the Cytotoxicity, Sensitization Irritation, and Acute Systemic Toxicity tests. HP 3D HR PA11 100% fresh powder was used for the Muscle Implantation test. HP 3D HR PA11 recycled (70% recycled/30% fresh) material was used for the Pyrogenicity test. 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 articles made from HP Agents & PA11 under recommended operating conditions as per the site preparation guide will meet the compliance requirements of USP Class I-VI and will be suitable for applications described in FDA’s guidance for Intact Skin Surface Devices.

2-pyrrolidone (2P) (CAS No. 616-45-5) is present in the 3D600/3D700 Fusing and Detailing Agents at <20% and 5% by weight, respectively. 2P is a Category 1B reproductive toxin according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS, as implemented by the EU Classification, Labeling and Packing Regulation No1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations. Based on HP internal testing (December 2019) of HP HR PA11 printed parts using GC/MS, 2-pyrrolidone can be present in the range of 0.29 - 0.34% by weight. No testing of HP 3D HR PA 11 printed parts has been conducted for reproductive/developmental toxicity.

2-Methyl-2H-isothiazol-3-one (MIT) (CAS No. 2682-20-4) is present in the 3D600/3D700 Fusing and Detailing Agents at <0.1% by weight in these formulations. MIT is a Category 1 skin sensitizer according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS, as implemented by the EU Classification, Labeling and Packing Regulation No1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations. MIT may be present in the final printed HD 3D HR PA 11 part.

It is the responsibility of each customer to determine that its use of HP Agents and PA11 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. HP PA11 powder is not intended to be used in medical device applications that constitute a non-temporary implant (i.e., that, in whole or in part, may be in contact with a patient’s skin, body fluids or tissues for more than 30 days.) 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 HP’s laboratories at testing time and those that applied for the purposes of the biocompatibility tests as 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 and PA11 material, HP cannot guarantee that the status of HP Agents and PA11 powder will remain unchanged or that it will qualify for USP Class I-VI Certification and or comply with FDA's guidance for Intact Skin Surface Devices in any particular use.

For additional information about HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.



Statement of Composition for Toy Applications

HP 3D600 Fusing and Detailing Agents and HP 3D HR PA12

Parts made with HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 have undergone the following tests:

1. Heavy Metal: No metals were detected in the study with a limit of detection of 2.0 ppm. The submitted samples comply with the soluble heavy metals requirements according to section 8.3.5 of ASTM F963-17.
2. Phthalates: No phthalates were detected down to 0.005% in the study. The submitted sample passed the applicable requirements for phthalates as recommended by the Consumer Product Safety Improvement Act of 2008, Section 108.
3. Bisphenol A (BPA): No Bisphenol A was detected in the sample down to 0.1 ppm.

The testing referred to above is typical of parts produced with HP 3D600/3D700 Fusing and Detailing Agents and fresh HP 3D HR PA11 powder³ on the HP Jet Fusion 3D 4200/4210 printers.

2-pyrrolidone (2P) (CAS No. 616-45-5) is present in the 3D600/3D700 Fusing and Detailing Agents at <20% and 5% by weight, respectively. 2P is a Category 1B reproductive toxin according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS, as implemented by the EU Classification, Labeling and Packing Regulation No1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations. Based on HP internal testing (December 2019) of HP HR PA11 printed parts using GC/MS, 2-pyrrolidone can be present in the range of 0.34 - 0.39% by weight. No testing of HP 3D HR PA 11 printed parts has been conducted for reproductive/developmental toxicity.

Newly printed parts from an HP 3D printer using HP 3D600/700/710 Agents and HP PA11 3D materials were tested to perform a targeted migration study for 2-pyrrolidone in both synthetic saliva and gastric fluid for incidental ingestion or "mouthing" (February 2020) with potential toy applications in mind. The migration study was performed in triplicate on the two samples by placing 4 squares of the sample in 50 ml of either synthetic saliva or synthetic gastric fluid for 2 hours at room temperature. 2-pyrrolidinone was analysed and quantified by LC-MS/MS analysis.

Migration test results

HP Material	Sample	Synthetic Gastric Fluid, mg/kg	Synthetic Saliva, mg/kg
HP HR PA11	1	0.30	0.40
	2	0.27	0.43
	3	0.30	0.38

2-Methyl-2H-isothiazol-3-one (MIT) (CAS No. 2682-20-4) is present in the 3D600/3D700 Fusing and Detailing Agents at <0.1% by weight in these formulations. MIT is a Category 1 skin sensitizer according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS, as implemented by the EU Classification, Labeling and Packing Regulation No1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations. MIT may be present in the final printed HD 3D HR PA 11 part.

³ Testing performed with 100% fresh powder.



It is the responsibility of each customer to determine that its use of HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 powder is safe and technically suitable to the customer's intended applications and consistent with the relevant regulatory requirements applicable to the customer's final product. HP's testing focused on the chemical composition of the printed parts and did not focus on physical requirements such as choking hazards. It is the responsibility of each customer to conduct their own testing to ensure that physical, mechanical, flammability, microbiological, acoustic, electrical, temperature, magnetism, and other relevant requirements for toys are met for their final product. Results may vary if the testing is performed under different conditions than those existing at HP's laboratories at testing time and those that applied for the purposes of the tests above. HP cannot guarantee compliance of HP 3D600 Fusing and Detailing Agents, HP 3D HR PA11 powder or any printed parts made with HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 with any legislation or industry standard that may be applicable to toys. Because of possible changes in the relevant industry standards, FDA and EU guidance, and other legal or regulatory requirements, as well as possible changes in HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 powder, HP cannot guarantee that the status of HP 3D600 Fusing and Detailing Agents and HP 3D HR PA11 powder will remain unchanged.

For additional information about HP 3D600 Fusing and Detailing Agents and HP 3D HR PA12, please contact our HP 3D Printing Materials team at 3dmaterials@hp.com.



No critical particle emissions from HP Jet Fusion 3D printers

Device performance undergoes strict safety consideration

Customers expect safe particle release behavior from their HP Jet Fusion 3D printing solutions. Evaluation needs to include different particle types potentially emitted – in particular fine and ultrafine particles. Indicative testing demonstrates that HP devices provide a high level of safety.

Fine dust emissions are negligible

Emissions of HP Jet Fusion 3D printing solutions in the fine particles size range of 0.3 to 10.0 micrometers (μm) are well below a variety of mandatory and voluntary environmental requirements, as indicative testing has shown.⁴

When compared against mandatory occupational limits and toxicologically based indoor air guide values, devices are far below relevant values. For example, the devices meet the fine particles criteria of the Germany AGW⁵ and the U.S. Permissible Exposure Limits (PELs)⁶. Accordingly, testing concluded that no health risks are expected when the devices are used and maintained as intended.

Ultrafine particles release is very low as well

For the extremely small ultrafine particles (UFPs) with a diameter of below 0.1 μm , concentrations resulting from the operation of HP Jet Fusion 3D printers are also quite low.⁷ Particle numbers lie well below the precautionary guide value of the German Blue Angel.⁸ And due to the UFPs' volatile nature, they do not hold the health hazardous potential associated with the solid consistency of particles in the ultrafine size range. Based on these observations, no health risks due to UFP release by HP Jet Fusion 3D printers have to be expected under reasonably foreseeable conditions of use as well.

Larger particles uncritical from a safety perspective

Particles with an average diameter of more than 10 μm generally have a lower exposure potential due to the propensity of these particles dripping out of the air. And, if inhaled, particles of this size are deposited in the upper regions of the human respiratory tract where they are subject to efficient clearance mechanisms. In addition to these physical considerations, the inherent chemical properties of the HP 3D materials do not indicate a health risk as they are not classified or labelled as hazardous according to the Globally Harmonized system of classification and Labelling of chemicals (GHS)⁹, the assessment criteria for mixtures in the European Union¹⁰, and applicable requirements in the United States.¹¹

⁴ HP commissioned indicative testing of HP Jet Fusion 3D 3200 and 4200 Printers operated with HP 3D PA12 material, carried out by the Fraunhofer Wilhelm-Klauditz-Institut (WKI), Braunschweig, Germany, 2016/2017.

⁵ Workplace limits (AGW), TRGS 900, German Ordinance of Hazardous Substances (GefStoffV), German Committee on Hazardous Substances (AGS), 2006 (as amended).

⁶ PELs-TWA, 29 CFR 1910.1000 Z-1 and Z-2, OSHA, 2006.

⁷ HP commissioned indicative testing of HP Jet Fusion 3D 3200 and 4200 Printers operated with HP 3D PA12 material, carried out by the Fraunhofer Wilhelm-Klauditz-Institut (WKI), Braunschweig, Germany, 2016/2017.

⁸ Basic criteria for award of the German Blue Angel (BA) environmental label for Office Equipment with Printing Function, RAL-UZ 171 or RALOUZ 205, RAL gGmbH.

⁹ GHS, ST/SG/AC. 10/30/Rev. 5, United Nations, 2013.

¹⁰ REG. (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, European Parliament and Council, 2008 (as amended).

¹¹ Occupational Safety and Health Standards, Toxic and Hazardous Substances, 1910.1200, OSHA, 2012 (as amended).

