

# HP 3D HR PA12

## *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 PA12. 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](http://www.hp.com/go/ecodata).

HP 3D HR PA12 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 PA12 can be imported without restriction:

- Australia (AICS)
- Canada (DSL, NDSL)
- Province 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 PA12.

#### Regulated Materials

HP 3D HR PA12 **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 colorants<sup>1</sup>
- Substances regulated as drugs and drug precursors or those requiring special permits for use

<sup>1</sup> 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.



- 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 PA12 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 PA12 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;
- Substances identified as "very persistent and/or very bioaccumulative" (vPvB) according to EU REACH criteria; and
- Substances as listed in Annex I and/or III of the Regulation (EU) No 2019/1021 are not intentionally used during the manufacturing process of PA 12.

### Transportation

HP 3D HR PA12 is Not Readily Combustible Solid of Division 4.1, Not Classified as a Flammable Solid<sup>2</sup>, 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.

<sup>2</sup> HP 3D HR PA12 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 Good, 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 66261.24 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	<0.0500 mg/kg
Selenium	<0.42 mg/kg
Silver	<0.37 mg/kg
Thallium	<0.49 mg/kg
Vanadium	<0.18 mg/kg
Zinc	5.9 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 12 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 <2.5 ppm by ASTM F963-11, section 8. 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 12 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
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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 12 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 12 were tested for bisphenol A and was below the detection level of 0.1 mg/kg in printed parts.

## Recyclability

HP 3D HR PA12 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](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](http://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.

## Automotive

Substances and heavy metals as itemized in the Global Automotive Declarable Substance List (GADSL) are not intentionally added to HP 3D HR PA12. The occurrence of substances restricted by GADSL can be excluded, except negligible amounts on the level of natural/technical impurities. HP 3D HR PA12 is not routinely analyzed for GADSL substances.

Materials information on PA12 have been entered into the International Material Data System (IMDS) and UL Prospector.



# ISO 10993, US FDA, and USP Class I-VI Medical Devices Statement

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

Original HP 3D600/3D700 Fusing and Detailing Agents and HP 3D HR PA12 material (“HP Agents & PA12 Material”) have undergone the following tests at a certified third-party laboratory:

1. Cytotoxicity – ISO 10993-5, Biological evaluation of medical devices – part 5: Tests for *in vitro* cytotoxicity. The test article extract showed no evidence of causing lysis or toxicity. The test article extract met the requirements of the test.
2. Sensitization and irritation – ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
  - a. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test.
  - b. The test article met the requirements of the intracutaneous injection in rabbits with test article extracts of 0.9% sodium chloride USP solution and sesame oil, NF.
3. Acute systemic toxicity – ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity. There was no mortality or evidence of systemic toxicity from the extracts of 0.9% sodium chloride USP solution and sesame oil, NF injected into mice. Each test article extract met the requirements of the study.
4. Muscle implantation
  - a. ISO 10993-6, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation. The test article was implanted for four weeks. The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article caused no reaction in the tissue as compared to the negative control article.
  - b. USP, General Chapter <88>, Biological Reactivity Tests, In vivo – Muscle implantation. The test article was implanted for seven days and the implanted test article met the USP requirements.
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 total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.
6. Hemolysis – ISO 10993-4, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood. The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the test article extract was 16.0%. The test article in direct contact with blood was non-hemolytic and the test article extract was hemolytic.
7. Genotoxicity – ISO 10993-3, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity and OEC 471, Guideline for Testing of Chemicals, Bacterial Reverse Mutation Test. The DMSO and saline test article extracts were considered to be nonmutagenic to *Salmonella typhimurium* tester strains TA98; TA100, TA1535, and TA1537, and to *Escherichia coli* tester strain WP2 *uvrA*.

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 & PA12 Material. HP 3D HR PA12 fresh and recycled (80% recycled/20% fresh) material was used for the Cytotoxicity, Sensitization, Irritation, and Acute Systemic Toxicity tests. HP 3D HR PA12 100% fresh powder was used for the USP Muscle Implantation test. HP 3D HR PA12 recycled (80% recycled/20% fresh) material was used for the Pyrogenicity, Hemolysis, Genotoxicity, and muscle implantation (ISO 10993) tests. 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 & PA12 Material under recommended operating conditions as per the site preparation guide will meet the testing stated above.

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 PA12 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 12 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 12 part.

It is the responsibility of each customer to determine that its use of HP Agents & HP HR PA12 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 & PA12 Materials, HP cannot guarantee that the status of HP Agents & PA12 Materials will remain unchanged or that it will qualify and or comply with ISO 10993, US FDA's guidance or USP Class I-VI Certification for any particular use.

For additional information about HP 3D600/3D700 Fusing and Detailing Agents and HP 3D HR PA12, please contact our HP 3D Printing Materials team at [3dmaterials@hp.com](mailto: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 PA12 have undergone the following tests:

1. Heavy Metal: No metals were detected in the study with a limit of detection of 2.5 ppm. The submitted samples comply with the soluble heavy metals requirements according to section 4.3.5.2 2(b) of ASTM F963-11.
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.

HP believes that the testing referred to above is typical of parts produced with HP 3D600/3D700 Fusing and Detailing Agents and fresh HP 3D HR PA12 powder<sup>3</sup> on the HP Jet Fusion 3D 3200 and 4200 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 PA12 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 12 parts has been conducted for reproductive/developmental toxicity.

Newly printed parts from an HP 3D printer using HP 3D600/700/710 Agents and HP PA12 materials were tested to 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 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 PA12	1	0.44	0.47
	2	0.41	0.49
	3	0.52	0.49

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 12 part.

It is the responsibility of each customer to determine that its use of HP 3D600 Fusing and Detailing Agents and HP 3D HR PA12 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 PA12 powder or any printed parts made with HP 3D600 Fusing and Detailing Agents and HP 3D HR PA12 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 PA12 powder, HP cannot guarantee that the status of HP 3D600 Fusing and Detailing Agents and HP 3D HR PA12 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](mailto: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 ( $\mu\text{m}$ ) are well below a variety of mandatory and voluntary environmental requirements, as indicative testing has shown.<sup>4</sup>

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 AGW<sup>5</sup> and the U.S. Permissible Exposure Limits (PELs)<sup>6</sup>. 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  $\mu\text{m}$ , concentrations resulting from the operation of HP Jet Fusion 3D printers are also quite low.<sup>7</sup> Particle numbers lie well below the precautionary guide value of the German Blue Angel.<sup>8</sup> 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  $\mu\text{m}$  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)<sup>9</sup>, the assessment criteria for mixtures in the European Union<sup>10</sup>, and applicable requirements in the United States.<sup>11</sup>

<sup>4</sup> 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.

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

<sup>6</sup> PELs-TWA, 29 CFR 1910.1000 Z-1 and Z-2, OSHA, 2006.

<sup>7</sup> 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.

<sup>8</sup> 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.

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

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

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

