

HP 3D High Reusability PP enabled by BASF

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 PP enabled by BASF. 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 PP enabled by BASF is a polypropylene powder designed 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 3D600/3D700/3D710 Agents statement for similar information on the agents.

Regulatory Summary

Chemical Inventory Status

The following countries have chemical inventory requirements, and HP 3D HR PP enabled by BASF 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 PP enabled by BASF.

Regulated Materials

HP 3D HR PP enabled by BASF **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

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.



- Substances regulated as drugs and drug precursors or those requiring special permits for use
- 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 PP enabled by BASF 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 No1272/2008/EC (CLP)), US HazCom 2012, and other country-specific GHS regulations.

HP 3D HR PP enabled by BASF 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 PP enabled by BASF 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.

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 <0.05 mg/Kg

² HP 3D HR PP enabled by BASF 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.



Arsenic	<0.15 mg/Kg
Barium	<0.055 mg/Kg
Beryllium	<0.055 mg/Kg
Cadmium	<0.10 mg/Kg
Chromium	<0.075 mg/Kg
Cobalt	<0.070 mg/Kg
Copper	<0.20 mg/Kg
Lead	<0.10 mg/Kg
Mercury	<0.083 mg/Kg
Molybdenum	<0.050 mg/Kg
Nickel	<0.50 mg/Kg
Selenium	<0.22 mg/Kg
Silver	<0.15 mg/Kg
Thallium	<0.20 mg/Kg
Vanadium	<0.10 mg/Kg
Zinc	<0.30 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 3D600/3D700/3D710 Agents and HP 3D HR PP enabled by BASF 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. Chromium was not detected in fluids by ICP-MS analysis or in the powder by analysis according to SW6010B and therefore is not expected in printed parts.

Phthalates

Parts printed on an HP 3D printer using HP 3D600/3D700/3D710 Agents and HP 3D HR PP enabled by BASF were tested following the CPSC-CH-C1001 test method for regulated phthalates listed in table 2 and the results were <50 ppm.

Table 2. Phthalates Tested

Di-butyl phthalate (DBP)
Diisobutyl phthalate (DIBP)
Butyl benzyl phthalate (BBP)
Di(2-ethylhexyl) phthalate (DEHP)
Di-n-pentyl phthalate (DPENP/DPP)
Dicyclohexyl phthalate (DCHP)
Di(iso-nonyl) phthalate (DINP)
Di-n-hexyl phthalate (DnHP)

Recyclability



HP 3D HR PP enabled by BASF 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://h20195.www2.hp.com/v2/getpdf.aspx/c06289065.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 <https://www8.hp.com/us/en/hp-information/sustainable-impact.html>

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 PP enabled by BASF. The occurrence of substances restricted by GADSL can be excluded, except negligible amounts on the level of natural/technical impurities. HP 3D HR PP enabled by BASF is not routinely analyzed for GADSL substances.

Materials information on HP 3D HR PP enabled by BASF have been entered into the International Material Data System (IMDS).

ISO 10993 and US FDA Intact Skin Surface Devices Statement

HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D HR PP enabled by BASF

Original HP 3D600/3D700/3D710 Fusing and Detailing Agents and HP 3D HR PP material enabled by BASF ("HP Agents & PP Material") have met the requirements of the US Food and Drug Administration ("FDA") and ISO 10993 guidance for Intact Skin Surface Devices to the extent that the following guidelines and tests were 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 3D 5200/5210 printers over the range of available printmodes with HP Agents & PP Material. HP 3D HR PP recycled (80% recycled/20% fresh) material was used for the Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and Pyrogenicity 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 & PP 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.

2-pyrrolidone (2P) (CAS No. 616-45-5) is present in the 3D600/3D700/3D710 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 PP printed parts using GC/MS, 2-pyrrolidone can be present in the range of 0.072 - 0.075% by weight. No testing of HP 3D HR PP 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 3D600/3D700/3D710 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 PP part.

It is the responsibility of each customer to determine that its use of HP Agents & HP HR PP 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 & PP Materials, HP cannot guarantee that the status of HP Agents & PP Materials 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 3D600/3D700/710 Fusing and Detailing Agents and HP 3D HR PP, 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.³

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 AGW⁴ and the U.S. Permissible Exposure Limits (PELs)⁵. 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.⁶ Particle numbers lie well below the precautionary guide value of the German Blue Angel.⁷ 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)⁸, the assessment criteria for mixtures in the European Union⁹, and applicable requirements in the United States.¹⁰

³ HP internal tests were completed to assess the air quality impacts of the of HP MJF 5200 Printer operated with PP material. Both indoor and outdoor emissions were assed.

⁴ Workplace limits (AGW), TRGS 900, German Ordinance of Hazardous Substances (GefStoffV), German Comitte on Hazardous Substances (AGS), 2006 (as amended).

⁵ PELs-TWA, 29 CFR 1910.1000 Z-1 and Z-2, OSHA, 2006.

⁶ HP internal tests were completed to assess the air quality impacts of the of HP MJF 5200 Printer operated with PP material. Both indoor and outdoor emissions were assed.

⁷ 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.

⁸ GHS, ST/SG/AC. 10/30/Rev. 5, United Nations, 2013.

⁹ REG. (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, European Parliament and Council, 2008 (as amended).

¹⁰ Occupational Safety and Health Standards, Toxic and Hazardous Substances, 1910.1200, OSHA, 2012 (as amended).

