



We create chemistry

Product Information

Page 1 / 2

Product: **Ultrasint™ TPU01 for HP Jet Fusion Printer**

Revision: 5.03.2020

Version: 1.0

Contact:

BASF 3D Printing GmbH
Speyerer Straße 4
69115 Heidelberg, Germany
sales@basf-3dps.com

Ultrasint TPU01 fulfills the requirements for intact skin surface devices according to ISO 10993. This conclusion can be drawn based on the following tests and subsequent risk analysis:

- **In vitro Skin Irritation Testing- Human Skin Model:**
(ISO 10993-10 (2013); OECD Guideline No. 439)
- **In vivo Sensitization Testing- Local Lymph Node Assay:**
(ISO 10993-10 (2013); OECD Guideline No. 429)
- **Cytotoxicity Testing- XTT:**
(ISO 10993-5 (2009))

The testing indicated a cytotoxic potential in L929 cells, but neither an irritating potential to skin nor a sensitizing potential. After risk assessment based on the results of the 3 toxicological studies for biocompatibility performed with extracts of the test item, the conclusion was drawn that parts printed with Ultrasint TPU01 contain no harmful extractables. Therefore, **parts printed with Ultrasint TPU01 can be used for medical device applications that come into contact with intact human skin for long-term (> 30 days).**

Details of the risk assessment are available upon request.

BASF believes that the results from the above-referenced testing are representative of parts produced with fresh Ultrasint TPU01 powder on the HP Jet Fusion 5210 and 5200 3D Printing Solutions and with the available print mode for Ultrasint TPU01. Based on the results, BASF expects that similar parts, made from Ultrasint TPU01 under recommended operating conditions as per the site preparation guide, will also meet the requirements for intact skin surface devices according to ISO 10993. However, it is the responsibility of each customer to determine that their use of Ultrasint TPU01 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. Customers should conduct their own testing to ensure that this is the case.

For notice:

The biocompatibility tests were recorded on test specimen of the above referenced product to show compatibility of the material in general, the biocompatibility tests listed above are not part of any continuous production protocol.

Results may vary if the testing is performed under different conditions than those applied at BASF 3D Printing Solutions' laboratories at testing time and those employed for the purpose of

Product: Ultrasint™ TPU01 for HP Jet Fusion Printer

Revision: 05.3.2020

Version: 1.0

biocompatibility testing as stated above.

Furthermore, it is the customer's responsibility that its final product is compliant to the latest regulatory requirements. Because of possible changes in the relevant industry and quality standards, BASF 3D Printing Solutions cannot guarantee that the status of Ultrasint TPU01 will remain unchanged or that it will qualify for intact skin surface devices according to ISO 10993 in any particular use.

All information contained in this document is given in good faith and is based on sources believed to be reliable and accurate at the date of publication of this document.

It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed. The certificate is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g. via Internet) by others. Thus, neither partial nor full publication is allowed without written permission.

This product information was generated electronically and is valid without signature.