



We create chemistry

Product Information

Page 1 / 1

Product: Ultracur3D® ST 80

Revision: 16 August 2021

Version: 5.0

Contact:

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

3D printed test items of the above stated product have fulfilled the requirements of tests as stated below:

Cytotoxicity Testing- Neutral red:

(ISO 10993-5 (2009))

In vitro Skin Irritation Testing:

(OECD Guideline No. 439)

Human Skin Irritation Test:

(ISO 10993-10 (2013))*

In vitro Sensitization Testing- KeratinoSens™

(prEN ISO 10993-10 (2020))

*Patch test on 10 volunteers.

Additionally

In vivo Sensitisation Testing- Local Lymph Node Assay (ISO 10993-10 (2013); OECD Guideline No. 429) was also performed

The 3D printed test item, Ultracur3D® ST80, was found to be **no skin sensitizer** under the test conditions of this study, **when extracted with the polar extract** in 30 wt% ethanol solution (EtOH).

However, 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. The test assessments reflect only the test specimen and have to be retested on the final product. It remains the responsibility of the device manufacturers and/or end-users to determine the suitability of all printed parts for their respective application.

For notice:

We give no warranties, expressed or implied, concerning the suitability of above-mentioned product for use in any medical device and pharmaceutical applications.

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.