

BASF 3D Printing Solutions GmbH  
Speyerer Straße 4, 69115 Heidelberg, Germany

March 30<sup>th</sup>, 2023  
Christian Dully  
Director Operations and Supply  
Chain  
[christian.dully@basf-3dps.com](mailto:christian.dully@basf-3dps.com)

Page 1 of 2

## Product information on skin irritation and skin sensitization testing

Product name: Ultracur3D<sup>®</sup> Coat F+ Pure White

ID-Number: 1030642

### Test for skin irritation:

EN ISO 10993-23 (2021), Biological evaluation of medical devices – Part 23

### Tests for skin sensitization:

OECD 442D & ISO 10993-10 (2021), Biological evaluation of medical devices – Part 10

<b>Product</b>	Ultracur3D <sup>®</sup> Coat F+ Pure White
<b>Skin irritation</b>	All 10 volunteers exhibited no dermal changes in the test zone at 24h, 48h and 72h.
<b>Skin sensitization</b>	The extracts of the product "Ultracur3D Coat F+ Pure White, ATLaS-2023-4480" resulted in an induction of the luciferase activity of less than 1.5 times compared to the DMSO control and is therefore to be assessed as non-sensitizing.

The skin irritation and sensitization tests were recorded on test specimens of the above referenced product. The tests listed are not part of any continuous production protocol. The test assessments reflect only the test specimens and must be retested on the final products. It remains the responsibility of the device manufacturers and/or end-users to determine the suitability of all printed parts for their respective applications.

**BASF 3D Printing Solutions GmbH**  
Speyerer Straße 4, 69115 Heidelberg  
Germany

Phone: +49 6221 67417-900  
E-Mail: [sales@basf-3dps.com](mailto:sales@basf-3dps.com)  
Web: [www.forward-am.com](http://www.forward-am.com)

**Registered Office:**  
69115 Heidelberg  
Germany

**Commercial Register:**  
Amtsgericht Mannheim  
HRB 728371

**Managing Director:**  
Martin Back



Management  
System  
ISO 9001:2015  
ISO 14001:2015  
[www.tuv.com](http://www.tuv.com)  
ID 900003927

**F o r n o t i c e:**

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.

**Disclaimer:**

*The declaration 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 by BASF 3D Printing Solutions GmbH.*

*The aforementioned data or information is based on our current knowledge and experience. In view of the many factors that may affect processing and application of our product, these data do not relieve processors from carrying out their own investigations and tests; neither do these data imply any guarantee of certain properties, nor the suitability of the product for a specific purpose. Any descriptions, drawings, photographs, data, proportions, weights etc. given herein may change without prior information and do not constitute the agreed contractual quality of the product. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing laws and legislation are observed. This statement does not constitute the legally binding Safety Data Sheet.*