



Statement Regarding the Biological Safety of Addigy™ GPU 79AR8 000000 UV

Page 1 of 1

Covestro evaluated grades of thermoplastic polyurethanes (TPU) for skin contact. Such tested TPU materials may for example be used for *Wearables*. Addigy™ GPU 79AR8 000000 UV is an uncolored thermoplastic polyurethane which is not manufactured under Good Manufacturing Practice (GMP).

Addigy™ GPU 79AR8 000000 UV was tested for biological safety following the ISO 10993-1 biocompatibility testing requirements for Medical Device components with unlimited skin contact. The testing comprised the toxicological endpoints

- Cytotoxicity (ISO 10993-5),
- Skin irritation (ISO 10993-10) and
- Skin sensitization (ISO 10993-10).

All biocompatibility tests conducted were met by the product tested.

Overall, the available biocompatibility data give no indication of a cytotoxic, skin irritating or skin sensitizing potential of Addigy™ GPU 79AR8 000000 UV that would limit its use in contact with human skin.

Note: This statement does not qualify the material for medical applications. The Chinese testing standards GB/T16886.1, GB/T16886.5 and GB/T16886.10 are also fulfilled when a product meets ISO 10993-1, 10993-5 and 10993-10 respectively.

Note: *Version 1. This product safety and regulatory related information ("Information") – whether verbal, in writing or by ways of trial – is given in good faith but without warranty, express or implied. The Information is provided by Covestro Deutschland AG ("Covestro") without assumption of any liability. If any of the above mentioned regulations change after the date of declaration, this declaration is no longer valid. This statement expires on and is no longer valid after 31 Jan 2023, and Covestro reserves the right to withdraw or modify the statement at any time without notice. Our publication of revised product statements on the internet portal or elsewhere renders the superseded statements void.*

Our Information does not release you from the obligation to verify the Information provided (especially that contained in our safety data and technical data sheets), to check for updates of any Information provided by us and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of Information are beyond our control and, therefore, entirely your own responsibility.

Our products are sold in accordance with the current version of our standard Conditions of Sale.

This statement is exclusively for our customers and respective competent authorities. It is not intended for reproduction either in printed or electronic form (e.g. via internet) by others. Thus, neither partial nor full reproduction is allowed without written permission from Covestro.

Covestro Deutschland AG
D-51365 Leverkusen, Germany
CTO-HSEQ-PSRA
Product Safety & Regulatory Affairs

Date: 2021-01-14

Board of management: Dr. Markus Steilemann (chairman), Sucheta Govil, Dr. Klaus Schäfer, Dr. Thomas Töpfer
Chairman of the supervisory board: Dr. Richard Pott
Registered office: 51365 Leverkusen, Local court of Cologne, HRB 49892