



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.

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