



March 15, 2021

Covestro LLC
Product Safety & Regulatory Affairs
1 Covestro Circle
Pittsburgh, PA 15205
Phone: 412 413 4753
e-mail: paul.kolesar@covestro.com

Kalash Jhamb
Quality Assurance Manager
Malema Sensors
kalash@malema.com

Dear Mr. Jhamb:

Responding to your request, we are providing you with the following information on our product **TEXIN RxT76D 000000**:

Biocompatibility of TEXIN RxT76D 000000 was evaluated by testing products TEXIN 5270, TEXIN RxT90AR 000000 and Desmopan 9370A 000000 according to USP Plastic Class VI and ISO Standard 10993-1 requirements. TEXIN5270, TEXIN RxT90AR 000000 and Desmopan 9370A 000000 contain the same base resin as TEXIN RxT76D 000000. TEXIN 5270, TEXIN RxT90AR 000000 and Desmopan 9370A 000000 were formulated to contain equal or higher levels of additives than used in TEXIN RxT76D 000000. The formula for TEXIN RxT76D 000000 used only additives which were included in the tested products. TEXIN 5270, TEXIN RxT90AR 000000 and Desmopan 9370A 000000 met the USP Plastic Class VI and ISO 10993-1 testing requirements listed below. Since TEXIN 5270, TEXIN RxT90AR 000000 and Desmopan 9370A 000000 met USP Plastic Class VI and ISO 10993-1 testing requirements, it is expected that TEXIN RxT76D 000000 would also meet these requirements.

Prior to testing, sample plaques of TEXIN 5270, TEXIN RXT90AR 000000 and Desmopan 9370A 000000 were sterilized by 6.0 Mrad dosage gamma irradiation and ethylene oxide. Tests conducted in accordance with Good Laboratory Practices include:

1. L929 MTT Cytotoxicity Test, ISO 10993-5
2. Kligman Maximization Test, ISO 10993-10
3. Intracutaneous Injection Test, ISO 10993-10
4. Systemic Injection Test, ISO 10993-11
5. Rabbit Pyrogen Test (Material Mediated), ISO 10993-11
6. Hemolysis – Rabbit Blood (Direct and Indirect), ISO 10993-4
7. *Salmonella Typhimurium* and *Escherichia Coli* Reverse Mutation Assay, ISO 10993-3
8. *In Vitro* Hemocompatibility Assay – Indirect, ISO 10993-4
9. Intramuscular Implantation Test, ISO 10993-6
10. Prothrombin Time Assay, ISO 10993-4 (Desmopan 9370A only)

The information contained herein is believed to be accurate as of the date of this document. The purpose for or manner in which you apply or utilize our products, technical assistance and information, whether verbal, written or by way of production evaluations, including any suggested formulations and recommendations, are beyond our control. It is imperative that you test our products to determine their suitability from a technical as well as health, safety, and environmental standpoint for your intended uses or applications. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee, expressed or implied, and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our technical assistance and information. Any statement or recommendation not contained herein shall not bind us. Covestro assumes no legal responsibility for use of or reliance upon the information in this document. Nothing herein shall be construed as a recommendation to use any product in conflict with any claim of any patent relative to any material or its use. Before working with our products, you must read and become familiar with all available information on the risks, proper use, and handling. Information is available in several forms, e.g., safety data sheets, product labels and other safe use and handling literature for chemical substance(s). The most current health and safety information regarding our products, including Safety Data Sheets (SDSs), is available at the Product Safety First website (www.productsafetyfirst.covestro.com). For further information contact your Covestro representative or the Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

11. Physicochemical Test For Plastics, USP 29 <661>
12. Test for Heavy Metals –Method I, USP 29 <231>
13. Sample Analysis by Inductively Coupled Plasma (ICP), EPA Method 3010A

Please contact us if you have any questions or if we can be of further assistance.

Sincerely,

Paul M. Kolesar Jr., Ph.D.
Senior Regulatory Affairs Specialist

cc: Doc
B. Yeh