Statement on BSE/TSE for TEXIN® Medical Grade Resins

Applicable to:

TEXIN RxT70A 000000	TEXIN RxT90A 000000	TEXIN RxT76D 000000
TEXIN RxT80A 000000	TEXIN RxT50D 000000	TEXIN RxS285 000000
TEXIN RxT85A 000000	TEXIN RxT65D 000000	TEXIN RxS292 000000

The TEXIN medical grade products listed above are synthetic organic materials that do contain substances derived from tallow sources. Our suppliers have assured us that processing conditions used in the production of these tallow derivative substances are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC, Commission Regulation 722/2012 and the Notes for Guidance EMA/410/01 Rev 3.

Process Conditions: Regulation 142/2011/EC Annex XIII Chapter XI

a) Transesterification or hydrolysis at at least: 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or

b) Saponification with NaOH 12 M (glycerol and soap) in a batch process at 95°C for 3 hours, or in a continuous process at 140°C, 2 bars (2,000 hPa) for 8 minutes; or

c) Hydrogenation at 160° C at 12 bars (12,000 hPa) for 20 minutes.

These conditions are considered to be sufficient to inactivate BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmitters. The conditions also meet the requirements of ISO 22442-1:2007 Annex C.5 regarding the processing of tallow derivatives used in medical devices.

Additionally, these tallow derivative substances are compliant with the U.S. Food and Drug Administration regulations regarding the use of prohibited cattle materials in food (21 CFR § 189.5) and cosmetics (21 CFR § 700.27), as prohibited cattle materials do not include tallow derivatives.

Version 5. The information contained herein is believed to be accurate as of the date of this document. If any of the above mentioned regulations change after the date of declaration, this information is no longer valid.

The manner in which you use 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. Therefore, it is imperative that you test our products to determine suitability for your processing and intended uses. Your analysis must at least include testing to determine suitability from a technical, health, safety, and environmental and regulatory standpoint. Such testing has not necessarily been done by Covestro, and Covestro has not obtained any approvals or licenses for a particular use or application of the product, unless explicitly stated otherwise.

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.

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Product Safety & Regulatory Affairs

Date: 2023-05-01