

Statement on BSE/TSE for TEXIN® Medical Grade Resins



Applicable to:

TEXIN RxT70A 000000

TEXIN RxT85A 000000

TEXIN RxT90A 000000

TEXIN RxT50D 000000

TEXIN RxT65A 000000

TEXIN RxS285 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. Covestro does not support the use of TEXIN RxT65D 000000 in food-contact applications. For further information regarding TEXIN medical grade resins, contact your Covestro representative or the Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

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