

FILTRATION BSE/TSE STATEMENT

Bis-Tris GMP

BioSpectra has evaluated the source of the filters used in the Bis-Tris manufacturing process through the Supplier Qualification Program. BioSpectra's approved Filtration Component Suppliers have stated that the filters may utilize components which are fabricated from plastic / polypropylene resin containing tallow-derived additives at trace levels, or which use a stearic acid as an activator in the vulcanization process. These materials are stated to be processed in accordance with EMA410/01 rev. 3 *Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathies via human and veterinary medicinal products*. Bis-Tris, Bio Excipient Grade manufactured by BioSpectra is not directly derived from or manufactured with any animal byproducts in any way from the primary, secondary, or tertiary processing levels.

Current Product Number
BTRI-3250

For further information, please contact info@biospectra.us



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