

BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

February 23rd, 2026

Revision 1

GENOTOXIC IMPURITIES STATEMENT

Tris

BioSpectra can state that none of the elements listed in ICH Q3D, USP <232>, and USP <233>, with the exception of Nickel, are added to the Tris, Bio Qualified Grade material or manufacturing process. Raney nickel is used as a catalyst in the Tris, Bio Qualified Grade manufacturing process. Tris, Bio Qualified Grade is manufactured using residual solvents Methanol and Nitromethane. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Tris, Bio Qualified Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Current Product Number
TRIS-6201
TRIS-6202

For further information, please contact Customer.Service@BioSpectra.us



Cassie Baun

Senior Compliance Specialist