BIOSPECTRA
Premium Pharmaceutical Ingredients

March 6th, 2025
Revision 3

NITROSAMINE STATEMENT

Tris API

BioSpectra can state that a Nitrosamine Risk Evaluation prepared in accordance with European Medicines Agency (EMA) requirements and US FDA Control of Nitrosamine Impurities in Human Drugs Guidance for Industry is available upon request for Tris, Bio Active Grade manufactured by BioSpectra.

Current Product Number
TRIS-2220
TRIS-2255
TRIS-2256
TRIS-2257

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Senior Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us