

TRIS HYDROCHLORIDE
COMPLIANCE STATEMENTS COVER LETTER

Tris Hydrochloride GMP – Bangor Manufactured

The Compliance Statements listed in Table 1 apply to all Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade Product Codes manufactured at BioSpectra’s Bangor, PA facility listed in Table 2 below.

Table 1. Compliance Statements

Compliance Statement Name
Allergen
Animal Origin
BSE/TSE
Catalysts
Certificate of Origin
Elemental Impurities
Formaldehyde
Genotoxic Impurity
Gluten Free
Genetically Modified Organisms (GMO)
GMP
Imidazole
Ingredient Declarations
Irgafos
Melamine
Mycotoxin / Aflatoxin
Nitrosamine
Phthalate, Bisphenol, Dioxin
Process Flow Diagram
Proposition 65
REACH
Residual Solvents
Slip Agent
Stability
Supply Chain
TUPP

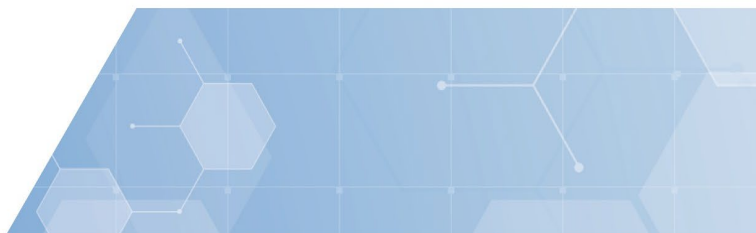


Table 2. Tris Hydrochloride Product Codes

Current Product Number	Historic Product Number
THCL-3220	TH3220
THCL-3221	TH3221
THCL-3250	TH3250
THCL-3251	TH3251
THCL-3252	TH3252
THCL-3253	TH3253
THCL-3254	TH3254
THCL-3255	TH3255
THCL-3256	TH3256
THCL-3257	TH3257
THCL-3258	TH3258
THCL-3259	TH3259
THCL-3260	N/A
THCL-4220	TH4220
THCL-4221	TH4221

For further information, please contact info@biospectra.us

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