

March 28<sup>th</sup>, 2024 Revision 1

## DIETHYLENE GLYCOL AND ETHYLENE GLYCOL STATEMENT

**Urea GMP** 

BioSpectra can state that the Urea, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra and its raw materials are not considered high risk for Diethylene Glycol and Ethylene Glycol contamination per the US FDA Guidance for Industry: Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol. BioSpectra does not specifically analyze Urea, Bio Excipient Grade, and Bio Pharma Grade or its raw materials for Diethylene Glycol and Ethylene Glycol.

Current Product Number
UREA-3220
UREA-3221
UREA-3222
UREA-3223
UREA-3224
UREA-3250
UREA-4205
UREA-4220

For further information, please contact info@biospectra.us

**Cassie Baun** 

Senior Compliance Specialist