

# BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

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Revision 1

## DIETHYLENE GLYCOL AND ETHYLENE GLYCOL STATEMENT

### L-Cystine DiHydrochloride

BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product line is Diethylene Glycol and Ethylene Glycol free based on this evaluation. BioSpectra does not analyze L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product line for Diethylene Glycol and Ethylene Glycol. L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product line is manufactured in accordance with the approved Supplier's ISO 9001:2015 certified quality management system, and is not considered high-risk 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.

Current Product Number
LCYS-4250

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)



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