

RE: Residual Solvents - Tetracaine Hydrochloride, USP (Cat# TE128)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Hexane	2	< 290 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

^{* 1,4-}Dioxane is present below the limit of 10 µg/g under the specification Limit of Free Ethylene Oxide and Dioxane as required by the NF monograph. ** Ethylene Glycol is present below the limit of 0.25% under the specification Limit of Ethylene Glycol and Diethylene Glycol as required by the NF monograph.

No Class 1 other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

CORPORATE HEADQUARTERS

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