

## **ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS**

(PPS283, Rev. 1.6, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in Toluene manufactured by Greenfield Global USA Inc. These OVIs, or Class 1, 2, and 3 Residual Solvents, are defined by the current USP/NF General Chapter <467> and International Conference on Harmonization Q3C Impurities: *Residual Solvents*.

**Class 1 Solvents:** Greenfield Global USA Inc. maintains dedicated storage and handling systems including separate tanks, lines and pumps for Toluene. Toluene may contain trace amounts of Benzene. Benzene is NOT used as a solvent, but may appear in Toluene as an impurity. Product specifications allow up to 300ppm of Benzene in Toluene. Actual Benzene content is reported on the lot-specific Certificate of Analysis. Greenfield Global USA Inc. neither uses nor has any reason to suspect that any other Class 1 solvents are produced in the manufacturing process. These Class 1 solvents include Carbon tetrachloride, 1,2-Dichloroethane, 1,1-Dichloroethene, and 1,1,1-Trichloroethane.

**Class 2 Solvents:** Greenfield Global USA Inc. maintains dedicated storage and handling systems including separate tanks, lines and pumps for our Toluene and neither uses nor has any reason to suspect that Class 2 solvents, including but not limited to Chloroform, 1,4-Dioxane, Methylene Chloride, Trichloroethylene, are produced in the manufacturing process. Toluene may contain trace amounts of Methanol. Methanol is NOT used as a solvent, but may appear in Toluene as an impurity. The typical level for Methanol content in Toluene is <2ppm, which is far below the concentration limit stated in Table 2 “Class 2 Residual solvents” found in the current USP/NF General Chapter <467>. Toluene itself would be considered a Class 2 Residual Solvent if found in any other solvent.

**Class 3 Solvents:** Although NOT used as solvents at any point in the manufacturing of Toluene, the following chemicals listed as Class 3 Residual Solvents may appear as impurities / related substances / low level contaminants in Toluene:

Ethyl Alcohol, Ethyl Acetate

Typical levels of these contaminants are in amounts that are far below the concentration limit stated in Table 3 “Class 3 Residual solvents” found in the current USP/NF General Chapter <467>.

**Other Residual Solvents:** Toluene does not contain any Other Residual Solvents found in Table 4 “Other Residual Solvents” found in the current USP/NF General Chapter <467>.