

**ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS**

(PPS281, Rev. 1.3, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in Tertiary Butyl Alcohol (Tert-Butanol, TBA) 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 a dedicated manufacturing facility for Tertiary Butyl Alcohol (Tert-Butanol, TBA) and neither uses nor has any reason to suspect that any Class 1 solvent is produced in the manufacturing process. These Class 1 solvents include Benzene, 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 for Tertiary Butyl Alcohol (Tert-Butanol, TBA) 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.

**Class 3 Solvents:** Although NOT used as solvents at any point in the manufacturing Tertiary Butyl Alcohol (Tert-Butanol, TBA), the following chemicals listed as Class 3 Residual Solvents may appear as impurities / related substances / low level contaminants in Tertiary Butyl Alcohol (Tert-Butanol, TBA):

Ethyl Alcohol, Isopropyl Alcohol, n-Propyl Alcohol.

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