



ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS265, Rev. 1.7, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in Methyl Alcohol (Methanol, MeOH) – all grades – 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*.

NO CHEMICALS WHATSOEVER ARE USED AS SOLVENTS AT ANY POINT IN THE MANUFACTURE, FORMULATION OR PACKAGING OF ANY METHYL ALCOHOL (METHANOL, MeOH) PRODUCTS MANUFACTURED BY Greenfield Global USA Inc.

Class 1 Solvents: Greenfield Global USA Inc. maintains a dedicated manufacturing facility for Methyl Alcohol (Methanol, MeOH) 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 including separate tanks, lines and pumps for our Methyl Alcohol (Methanol, MeOH) 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.

Methyl Alcohol (Methanol, MeOH) 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 Methyl Alcohol (Methanol, MeOH) following chemicals listed as Class 3 Residual Solvents may appear as impurities / related substances / low level contaminants in Methyl Alcohol (Methanol, MeOH): Ethyl Alcohol – up to 60ppm

The amounts Ethanol contaminations in Methyl Alcohol (Methanol, MeOH) 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: Methyl Alcohol (Methanol, MeOH) does not contain any Other Residual Solvents found in Table 4 “Other Residual Solvents” found in the current USP/NF General Chapter <467>.

Actual amount of related substances / organic volatile impurities in Methyl Alcohol (Methanol, MeOH) vary. Product is tested for all suspected related substances and analytical results are reported on the Certificate of Analysis as Organic Volatile Impurities (OVI). Please refer to Certificate of Analysis for lot-specific data.