

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS248, Rev. 1.7, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in Ethyl Acetate – 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 ETHYL ACETATE MANUFACTURED BY Greenfield Global USA Inc.

Class 1 Solvents: Greenfield Global USA Inc. maintains dedicated storage and handling systems including separate tanks, lines and pumps for our Ethyl Acetate and neither uses nor has any reason to suspect that any Class 1 solvents are 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 Ethyl Acetate products 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.

Ethyl Acetate may contain trace amounts of methanol. Methanol is NOT used at any point of manufacturing of Ethyl Acetate and appears as related substance / low-level contaminant in Ethyl Acetate. The typical level for methanol content is far below the concentration limit stated in Table 2 “Class 2 Residual solvents” found in the current USP/NF General Chapter <467>.

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

Butyl Acetate, Ethanol, Isobutyl Acetate, Isopropyl Acetate, Methyl Acetate, 1-Propanol, 2-Propanol, Propyl Acetate.

Ethyl Acetate itself would be considered a Class 3 residual solvent if found in any other solvent.

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