



ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS268, Rev. 1.3, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in n-Butyl Alcohol (n-Butanol, NBA) – 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*.

Class 1 Solvents: Greenfield Global USA Inc. maintains a dedicated manufacturing facility for n-Butyl Alcohol 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 n-Butyl Alcohol 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 of n-Butyl Alcohol, the following chemicals listed as Class 3 Residual Solvents may appear as impurities / related substances / low level contaminants in n-Butyl Alcohol:

Ethyl Alcohol, Isopropyl Alcohol, IsoButyl 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>.

N-Butyl Alcohol itself would be considered a Class 3 residual solvent if found in any other solvent.

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