

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS234, Rev. 1.9, 02/18, KMC)

RE: Acetone – all grades sold by Greenfield Global USA Inc. – Organic Volatile Impurities, or Class 1, 2, and 3 Residual Solvents, as defined by the current USP monograph General Chapter <467> and ICH Q3C Guideline for Residual Solvents.

NO CHEMICALS WHATSOEVER ARE USED AS SOLVENTS AT ANY POINT IN THE MANUFACTURE, FORMULATION OR PACKAGING OF ACETONE 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 Acetone and neither uses nor has any reason to suspect that any Class 1 solvents are produced in the manufacturing process.

Acetone may contain trace amounts of Benzene. Benzene is NOT used as a solvent, but may appear in Acetone as a by-product. The typical level for Benzene content in Acetone is <2ppm.

Class 2 Solvents: Greenfield Global USA Inc. maintains dedicated storage and handling systems including separate tanks, lines and pumps for our Acetone and neither uses nor has any reason to suspect that Class 2 solvents, including but not limited to Chloroform, 1,4-Dioxane, Methylene Chloride, or Trichloroethylene are produced in the manufacturing process.

Acetone may contain trace amounts of methanol. Methanol is NOT used as a solvent, but may appear in Acetone as an impurity. The typical level for methanol content in Acetone is <200ppm, which is far below the concentration limit stated in Table 2 “Class 2 Residual solvents” found in current USP monograph General Chapter <467> and ICH Q3C Guideline.

Acetone may contain trace amounts of Cumene. Cumene is categorized as Class 2 Residual Solvents by USP General Chapter <467>. The typical levels of cumene content in Acetone is <5 ppm, which is far below the Option 1 limit.

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

Ethyl Alcohol, n-Propyl 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 current USP monograph General Chapter <467> and ICH Q3C Guideline..

Acetone may contain trace amounts of Cumene. Cumene is categorized as Class 2 Residual Solvents by ICH Q3C Guideline. The typical levels of cumene content in Acetone is <5 ppm.

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

Other Residual Solvents: Acetone does not contain any Other Residual Solvents listed in Table 4 “Other Residual Solvents” found in current USP monograph General Chapter <467> and ICH Q3C Guideline.