

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS235, Rev. 1.4, 02/18, KMC)

RE: **Acetonitrile (ACN)** – 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/NF** General Chapter <467>.

NO CHEMICALS WHATSOEVER ARE USED AS SOLVENTS AT ANY POINT IN THE MANUFACTURE, FORMILATION OR PACKAGING OF Acetonitrile (ACN) MANUFACTURED BY Greenfield Global USA Inc.

Class 1 Solvents: Greenfield Global USA Inc. maintains a dedicated manufacturing facility for Acetonitrile (ACN) 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 handling system for Acetonitrile (ACN) 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.

Although NOT used as solvents at any point in the manufacturing of Acetonitrile (ACN), the following chemicals listed as Class 2 Residual Solvents may appear as impurities / related substances / low level contaminants in Acetonitrile (ACN):

Methanol – up to 15ppm

Pyridine – up to 3ppm

The levels of Methanol and Pyridine content in Acetonitrile (ACN) are far below the concentration limits stated in Table 2 "Class 2 Residual solvents" found in the current **<u>USP/NF</u>** General Chapter <467>. Acetonitrile (ACN) 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 Acetonitrile (ACN), the following chemicals listed as Class 3 Residual Solvents may appear as impurities / related substances / low level contaminants in Acetonitrile (ACN): Acetone – up to 10ppm

The amount of Acetone contamination in Acetonitrile (ACN) is 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: Acetonitrile (ACN) does not contain any Other Residual Solvents found in Table 4 "Other Residual Solvents" found in the current <u>USP/NF</u> General Chapter <467>.

This statement is valid and in effect for all products and lots described herein until otherwise notified in writing by Greenfield Global USA Inc.