

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS260, Rev. 2.0, 02/18, KMC)

RE: Organic Volatile Impurities / Residual Solvents in Isopropyl Alcohol (Isopropanol, IPA) – 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 ISOPROPYL ALCOHOL (Isopropanol, IPA) PRODUCTS MANUFACTURED BY Greenfield Global USA Inc..

Class 1 Solvents: Greenfield Global USA Inc. maintains a dedicated manufacturing facility for Isopropyl Alcohol (Isopropanol, IPA) 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 Isopropyl Alcohol (Isopropanol, IPA) 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.

Isopropyl Alcohol (Isopropanol, IPA) may contain methanol. Methanol is NOT used as a solvent, but may appear in Isopropyl Alcohol (Isopropanol, IPA) as an impurity. The typical level for methanol content in Isopropyl Alcohol (Isopropanol, IPA) is <10ppm, which is far below the concentration limit stated in Table 2 “Class 2 Residual solvents” found in the **current USP/NF** General Chapter <467> and ICH.

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

Acetone up to 20ppm

Ethyl Alcohol up to 30ppm

n-Propyl Alcohol up to 150ppm

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>.

Isopropyl Alcohol (Isopropanol, IPA) itself would be considered a Class 3 residual solvent if found in any other solvent.

Other Residual Solvents: Isopropyl Alcohol (Isopropanol, IPA) does not contain any Other Residual Solvents found in Table 4 “Other Residual Solvents” found in the **current USP/NF** 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.