

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS260, Rev. 1.9, 08/15, PJM)

RE: Organic Volatile Impurities / Residual Solvents in Isopropyl Alcohol (Isopropanol, IPA) – all grades – manufactured by PHARMCO-AAPER. 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 PHARMCO-AAPER.

Class 1 Solvents: PHARMCO-AAPER 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: PHARMCO-AAPER 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 PHARMCO-AAPER.