

ORGANIC VOLATILE IMPURITIES / RESIDUAL SOLVENTS

(PPS250, Rev. 1.8, 01/16, PJM)

RE: Organic Volatile Impurities / Residual Solvents in Ethyl Alcohol (Ethanol, EtOH) – 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 ETHYL ALCOHOL (Ethanol, EtOH) PRODUCTS MANUFACTURED BY PHARMCO-AAPER.

Class 1 Solvents: PHARMCO-AAPER maintains a dedicated manufacturing facility for Ethyl Alcohol (Ethanol, EtOH) 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 Ethyl Alcohol (Ethanol, EtOH) 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.

Ethyl Alcohol (Ethanol, EtOH) may contain up to 40ppm of Methanol. Methanol is NOT used at any point of manufacturing of Ethyl Alcohol (Ethanol, EtOH) and appears as related substance / low-level contaminant in Ethyl Alcohol (Ethanol, EtOH). The level for methanol content in Ethyl Alcohol (Ethanol, EtOH) is far below the concentration limit stated in Table 2 “Class 2 Residual solvents” found in the current USP/NF General Chapter <467>.

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

Isopropyl Alcohol (2-Propanol) – up to 30ppm

n-Propyl Alcohol (1-propanol) – up to 30ppm

The amount of Isopropyl Alcohol (Isopropanol, IPA) contamination in Ethyl Alcohol (Ethanol, EtOH) are far below the concentration limit stated in Table 3 “Class 3 Residual solvents” found in the current USP/NF General Chapter <467>.

Ethyl Alcohol (Ethanol, EtOH) itself would be considered a Class 3 residual solvent if found in any other solvent.

Other Residual Solvents: Ethyl Alcohol (Ethanol, EtOH) does not contain any Other Residual Solvents.

Actual amount of related substances / organic volatile impurities in Ethyl Alcohol vary. Product is tested for all suspected related substances and analytical results are reported on the Certificate of Analysis as Organic Volatile Impurities (OVI). Please refer to Certificate of Analysis for lot-specific data.