

March 9th, 2018

Residual Solvents and Organic Volatile Impurities Statement

Packaged ethyl alcohol products (190 to 200 US proof, equivalent to 95 to 100% by volume)

Residual Solvents

No chemicals whatsoever are actually used as solvents, at any point in the manufacture, formulation, or packaging of any ethyl alcohol products by Greenfield Global.

However, ethyl alcohol itself does have solvent properties. As well, several chemicals are used or produced as impurities during the manufacture, formulation, or packaging of ethyl alcohol by Greenfield Global, that, though NOT used as solvents at any point in the manufacturing, formulation, or packaging process, may appear as impurities in ethyl alcohol offered for sale by Greenfield Global, and as well are listed in section <467> *Residual Solvents* in the General Chapters of the US Pharmacopoeia.

Though NOT used as solvents, the following chemicals listed in the USP in the general chapters, article <467> *Residual Solvents* and in the ICH guidelines, are used or produced in the manufacturing process, at Greenfield Global manufacturing and packaging facilities:

- Acetic acid
- Acetone
- Ethyl acetate
- Ethyl alcohol
- Ethyl Ether
- 1-propanol (n-propanol)
- 2-propanol (isopropyl alcohol)
- Tertiary butyl alcohol (TBA)
- Toluene
- Methanol

None of the above are ICH Class 1 solvents.

Methanol and Toluene are the only ICH Class 2 solvents listed above.

The remainder of the chemicals listed above are listed in the USP and/or the ICH guidelines as Class 3 solvents, with the exception of tertiary butyl alcohol (TBA), which is not listed in any part of Class 1 to Class 4 in section <467> of the USP.

None the chemicals listed in *Table 1: Class 1 Residual Solvents* or *Table 4: Other Residual Solvents* of article <467> in the USP are used or produced in the manufacturing process and/or in plant equipment cleaning, at Greenfield Global manufacturing and packaging facilities. Acetic acid, acetone, ethyl acetate, ethyl ether, methanol, methyl ethyl ketone, methyl isobutyl ketone, 2-propanol (isopropyl alcohol), tertiary butyl alcohol (TBA), and toluene, are used as denaturants to denature the final product alcohol for those customers that require a denatured alcohol. They

are added to ethyl alcohol in accordance with Excise-approved denaturant formulations, so as to provide various denatured alcohol formulations to those customers that require them.

As well, acetic acid, acetone, ethyl acetate, ethyl ether, methanol, 1-propanol, and 2-propanol, are produced as side reactions during the fermentation step in the ethyl alcohol manufacturing process, and may be present as impurities in ethyl alcohol.

None of them are used as ingredients in the manufacture of ethyl alcohol or as cleaning agents. However, they are produced or used for denaturing in the manufacturing facility, as described above. Their use is controlled and these chemicals would not, if tested in the above ethyl alcohol products, be over the value listed in the USP <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

Organic Volatile Impurities Values Reported on Certificates of Analyses

Greenfield Global provides test results for the following organic volatile impurities on the Certificate of Analysis for ethyl alcohol products:

Methanol - Though not used as a solvent at any point during ethyl alcohol manufacture by Greenfield Global, methanol is produced as a side reaction during ethyl alcohol fermentation. The USP monographs for *Alcohol* and *Alcohol, Dehydrated*, require that methanol be measured by gas chromatography. The measured value is reported on our Certificate of Analysis. Our specification for methanol in our ethyl alcohol products is 75ppm maximum.

Acetaldehyde plus acetal - Though not used as a solvent at any point during ethyl alcohol manufacture by Greenfield Global, acetaldehyde is produced as a side reaction during ethyl alcohol fermentation. The USP monographs for *Alcohol* and *Alcohol, Dehydrated*, require that acetaldehyde plus acetal be measured by gas chromatography. The measured value is reported on our Certificate of Analysis. Our specification for acetaldehyde plus acetal in our ethyl alcohol products is 10ppm maximum.

Benzene - Benzene is not used as a solvent during ethyl alcohol manufacture by Greenfield Global, nor produced as a side reaction, nor added at any point in the manufacturing process. However, the USP monographs for *Alcohol* and *Alcohol, Dehydrated*, require that benzene be measured by gas chromatography. The measured value is reported on our Certificate of Analysis. Our specification for benzene in our ethyl alcohol products is 2ppm maximum.

Sum of all other areas - The USP monographs for *Alcohol* and *Alcohol, Dehydrated*, require that the sum of all other areas be measured by gas chromatography. The measured value is reported on our Certificate of Analysis. Our specification for the sum of all other areas in our ethyl alcohol products is 300ppm maximum.



Shannon Smith
Quality Assurance Coordinator