

June 18<sup>th</sup>, 2018

## Residual Solvents and Organic Volatile Impurities Statement

### Packaged isopropyl alcohol 70% and isopropyl alcohol 99% products

Greenfield Global manufactures ethyl alcohol at its bulk manufacturing facilities, formulates denatured ethyl alcohol products at its bulk manufacturing and packaging facility, packages isopropyl alcohol and methanol at its packaging facility, and formulates and packages isopropyl alcohol 70% at its packaging facility.

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

However, isopropyl alcohol products themselves do have solvent properties.

Though NOT used as solvents at any point in the manufacturing, formulation, or packaging process for isopropyl alcohol products offered for sale by Greenfield Global, the following chemicals listed in the USP in the general chapters, article <467> *Residual Solvents*, in the EP general chapters, 5.4 *Residual Solvents*, and in the ICH guidelines, are used or may appear as impurities in the manufacturing and packaging process of isopropyl alcohol products, at Greenfield Global manufacturing and packaging facilities:

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

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 EP 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 the USP, EP, or ICH guidelines 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, 2-propanol (isopropyl alcohol), tertiary butyl alcohol (TBA), and toluene, are used as denaturants to denature ethyl 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 ethyl alcohol formulations to those customers that require them.

The chemicals described above would not, if tested in the above isopropyl alcohol products, exceed the values listed in the USP <467> *Residual Solvents*, EP 5.4 *Residual Solvents*, or the ICH guidelines.

Additionally, benzene content is tested for every lot of isopropyl alcohol 99% USP/EP that is packaged by Greenfield Global. Benzene is not used as a solvent at any point in the manufacturing or packaging process, nor is it expected to be present in any other isopropyl alcohol product; however testing for benzene is required per the EP monograph for isopropyl alcohol 99%. We perform testing, confirm, and indicate on the certificate of analysis that each lot of isopropyl alcohol 99% USP/EP packaged by Greenfield Global contains less than 2ppm benzene.



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