

December 21<sup>st</sup>, 2017

## Residual Solvents Statement

Specially Denatured Alcohol SDA-40-2 (190-200 US Proof)

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### 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 products 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 products 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, or as an ingredient in the formulation of the product at Greenfield Global manufacturing and packaging facilities:

- |                 |                          |                                  |
|-----------------|--------------------------|----------------------------------|
| ▪ Acetic acid   | ▪ Ethyl ether            | ▪ 1-propanol (n-propanol)        |
| ▪ Acetone       | ▪ Methanol               | ▪ 2-propanol (isopropyl alcohol) |
| ▪ Ethyl acetate | ▪ Methyl ethyl ketone    | ▪ Toluene                        |
| ▪ Ethyl alcohol | ▪ Methyl isobutyl ketone |                                  |

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.

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), 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 SDA-40-2. 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 ICH guidelines for the above chemicals.

SDA-40-2 contains tertiary butyl alcohol (TBA) and brucine sulfate as part of its formulation.

Tertiary butyl alcohol is present in SDA-40-2 at the level of 0.125% v/v. It does not appear in section <467> of the USP. No Class 1, Class 2, Class 3, or Class 4 solvents are used at any point in the manufacture of TBA. No Class 1, Class 2, or Class 4 solvents are known to be present in TBA used by Greenfield Global in the formulation of SDA-40-2. However, the following chemicals listed as Class 3 Residual Solvents may appear as impurities, related substances, or low level contaminants in TBA - ethyl alcohol, isopropyl alcohol, and n-propanol. 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 General Chapters <467> of the USP.



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