

May 3rd, 2018

Residual Solvents and Organic Volatile Impurities Statement

Packaged methanol and denatured ethyl alcohol products

SDAG-1, SDA 3-A, SDAG-2, SDAG-3, SDAG-9, SDAG-10, SDA 23-A, SDAG-13, DA-2A, DA-2I, and DA-2O

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, our alcohol products themselves do have solvent properties. As well, several chemicals are used or produced as impurities during the manufacture, formulation, or packaging of these 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 these 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, 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 DA-20 or SDAG-3, 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 alcohol products, be over the value listed in the ICH guidelines for the above chemicals.

SDAG-1 95% and anhydrous, SDA-3A 190 and 200 proof, and SDAG-2 95% and anhydrous contain methanol as denaturant, at the levels of 4.76 v/v%, 4.76 v/v%, and 9.09 v/v% respectively. Full strength methanol packaged and sold by Greenfield Global contains 100% methanol. Aside from the methanol ingredient in SDAG-1, SDA-3A, SDAG-2, and in methanol, the other denaturants described above (acetic acid, acetone, ethyl acetate, ethyl ether, 2-propanol, and toluene), if tested in SDAG-1, SDA-3A, SDAG-2 or methanol, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

SDAG-9 95% and anhydrous contain isopropyl alcohol as denaturant at the level of 4.76 v/v%. Aside from the isopropyl alcohol ingredient in SDAG-9, the other denaturants described above (acetic acid, acetone, ethyl acetate, ethyl ether, methanol, and toluene), if tested in SDAG-9, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

SDAG-10 95% and anhydrous and SDA-23A 190 and 200 proof contain acetone as denaturant at the levels of 9.09 v/v% and 7.41 v/v% respectively. Aside from the acetone ingredient in SDAG-10 and SDA-23A, the other denaturants described above (acetic acid, ethyl acetate, ethyl ether, 2-propanol, methanol, and toluene), if tested in SDAG-10 or SDA-23A, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

SDAG-13 95% and anhydrous contain ethyl acetate as denaturant at the level of 0.99 v/v%. Aside from the ethyl acetate ingredient in SDAG-13, the other denaturants described above (acetic acid, acetone, ethyl ether, 2-propanol, methanol, and toluene), if tested in SDAG-13, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

DA-2A 95% and anhydrous contain methanol and ethyl acetate as denaturants at the levels of 13.7 v/v% and 0.85 v/v% respectively. Aside from the methanol and ethyl acetate ingredients in DA-2A, the other denaturants described above (acetic acid, acetone, ethyl ether, 2-propanol, and toluene), if tested in DA-2A, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.

DA-2I 95% and anhydrous contain isopropyl alcohol and ethyl acetate as denaturants at the levels of 7.0 v/v% and 3.0 v/v% respectively. Aside from the isopropyl alcohol and ethyl acetate ingredients in DA-2I, the other denaturants described above (acetic acid, acetone, ethyl ether, methanol, and toluene), if tested in DA-2I, would not exceed the limits listed in the <467> *Residual Solvents* or the ICH guidelines for the above chemicals.



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