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01 January 2020

Residual Solvents in Calumet Refining White Mineral Oils and Petrolatum

Residual Solvents (also called Organic Volatile Impurities) appears as a General Chapter <467> of the USP. Three classes of solvents are ranked, ranging from those of most concern, Class 1, which should not be used in Pharmaceutical products, to those of Class 3, that are regarded as less toxic and of lower risk. No Class 1 solvents are used in the manufacture of Calumet Refining white mineral oils or petrolatum. Also, none of the solvents listed in Table 4 of General Chapter <467> are used in processing our mineral oils or petrolatum.

Toluene, a Class 2 solvent, may be used in the dewaxing process that is used to make raw petrolatum. However, our petrolatum feedstocks have been analyzed for toluene and are found to comply with the limits shown in Table 2 of General Chapter <467>. Methyl ethyl ketone (MEK), a Class 3 Solvent, may also be used in the manufacture of the feedstock petrolatum. Our routine testing demonstrates the MEK content also complies with General Chapter <467>. All of our raw petrolatum feedstocks are severely hydrotreated as the first processing step at our plant in Karns City, PA. In this process any residual toluene and MEK should be converted to saturated hydrocarbons and are then removed from the petrolatum in a stripper unit (distillation) immediately following hydrogenation. A final processing step involves filtration (adsorption) over activated bauxite. Our petrolatum products are not exposed to any other organic solvents during final processing.

White mineral oils may be exposed to 2-propanol (a Class 3 Solvent) during processing. The alcohol is removed by a stripping process and by filtration over bauxite. Data from GC testing on intermediate mineral oil process streams consistently show that the 2-propanol content is less than 400 ppm. The limit for Class 3 solvents in General Chapter <467> is 5,000 ppm. Our white mineral oils are not exposed to any other organic solvents during final processing.

Calumet Refining white mineral oils and petrolatum fully comply with the Residual Solvents requirements in the current USP. Our products also comply with section 5.4, Residual Solvents, in the European Pharmacopoeia and with the CPMP/ICH/283/95 Guidelines for Residual Solvents.

Please feel free to contact me should you have any further questions.

Sincerely,

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