



2780 Waterfront Pkwy. E. Dr. Suite 200 Indianapolis, IN 46214
Phone: 317-328-5660 Fax: 317-328-5668 Sales: 1-800-437-3188 www.calumetspecialty.com

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Residual Solvents in Calumet Penreco White Mineral Oils and Petrolatums

Residual Solvents (also called Organic Volatile Impurities) appears as a General Chapter <467> of the USP. Three classes of solvents are ranked 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. There are no Class 1 solvents used in the manufacture of Calumet Penreco white mineral oils or petrolatums. Besides the three classes, there are also solvents listed in Table 4 of Section 467. None of the solvents in this table are used in processing our mineral oils or petrolatums.

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 found to comply with the limits shown in Table 2 of section 467 of the USP. Methyl ethyl ketone (MEK), a Class 3 Solvent, may also be used in the manufacture of the feedstock petrolatums. Our testing has shown that the MEK content also complies with section 467 of the USP. 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 petrolatums 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 Section 467 of the USP is 5,000 ppm. Our white mineral oils are not exposed to any other organic solvents during final processing.

Calumet Penreco white mineral oils and petrolatums 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.

Michael Lapota
Technical Service Manager
Calumet Specialty Products Partners, L.P.