



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

01 January 2017

To Our Valued Customers,

This general regulatory letter is in regard to the following Calumet Penreco products:

**Mineral Oils USP and NF**  
**Technical Mineral Oils**  
**Petrolatum USP and White Petrolatum USP (Including Ointment Bases)**  
**Mineral Jellies**

#### **FDA Registration**

Calumet Penreco plants in Karns City, PA and Dickinson, TX follow cGMP as defined in 21 CFR 211 and they are registered with the FDA as Drug Establishments. Copies of FDA Form 2656 are available on request.

#### **ISO 9001:2008**

Both Calumet Penreco plants have current Certificates of Compliance from Lloyd's Register Quality Assurance, Inc. (LRQA) of Houston, TX. Copies of the Certificates are available on request and also in the Certifications area on this website.

#### **Shelf life / Stability**

A retain sample of every batch is held for three years after the date of manufacture. We test these samples on a spot basis to make sure that they meet all of the USP/NF specifications. We suggest to customers who may need to put an expiration date on their products, use a date of two years after the date of manufacture that appears on our Certificates of Analysis. This conforms to the FDA's suggestion in cGMP of keeping samples for one year past the date of expiration.

#### **Pharmaceutical Applications**

In general, USP/ NF grade mineral oils and USP grade petrolatums meet their corresponding pharmacopeias in Europe and Japan. However, there are certain properties found in the various monographs that do not overlap. Therefore we need to review the specific product before we can make a statement regarding other pharmacopeias.



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](http://www.calumetspecialty.com)

### **Cosmetic Applications**

Calumet Penreco USP/NF white mineral oils, USP petrolatums (including ointment bases), and mineral jellies), are appropriate for use in cosmetic products in the US, Canada, EU, Japan and other countries throughout the world. The INCI (International Cosmetic Ingredient Dictionary) name for all of our oils is "Mineral Oil". The INCI name for all of our petrolatums is "Petrolatum".

### **Food Applications**

Calumet Penreco USP/NF grade mineral oils, technical grade oils, and USP petrolatums are entirely petroleum derived. They contain no plant-, animal-, or microbial-derived components and therefore they contain no proteins, glutens, fatty acids, pesticide residues, or microbial-based materials. These products also contain no genetically modified organisms (GMO's).

Calumet Penreco USP petrolatums (including ointment bases) meet FDA regulation 21 CFR 172.880 for certain direct food applications. They also meet 21 CFR 178.3700 for indirect food contact and they meet 21CFR 573.720 for use in animal feed.

Calumet Penreco USP/NF grade mineral oils meet FDA regulation 21 CFR 172.878 for certain direct food applications. The USP/NF grade mineral oils and the technical grade mineral oils (Parols) meet FDA regulation 21 CFR 178.3620 (b) for indirect food contact. All of the Calumet Penreco oils listed above meet FDA regulation 21 CFR 573.680 for use in animal feed.

Calumet Penreco USP/NF grade mineral oils, technical grade oil, and USP petrolatums meet numerous other CFR regulations involving indirect food contact. Please contact us regarding your specific application.

Calumet Penreco USP/NF grade mineral oils, technical grade oil, and USP petrolatums have no nutritional value when ingested. They generally pass through the digestive system without absorption.

### **Food Chemical Codex (FCC)**

Calumet Penreco USP/NF grade mineral oils and USP grade petrolatums meet their respective monographs in the Food Chemical Codex (FCC).

### **Certified VEGAN**

The Drakeol 7 LT MIN OIL NF, Drakeol 9 LT MIN OIL NF, Drakeol 10 LT MIN OIL NF, Drakeol 13 LT MIN OIL NF, Drakeol 21 MIN OIL USP, Drakeol 34 MIN OIL USP and Drakeol 600 MIN OIL USP products are all certified vegan by the American Vegetarian Association.



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

### **BSE/TSE Statement**

The Calumet Penreco products listed above are manufactured entirely from petroleum sources (non-synthetic). They contain no animal or plant derived materials and therefore there is no possibility of any Bovine, Ovine, Porcine, or Caprine derived diseases being transmitted by the use of these materials.

### **Allergens Statement**

The 7th Amendment of the European Cosmetics Regulation lists allergens that may be found in cosmetics. None of the Calumet Penreco products shown above contain any of the substances on the list. In addition, these products do not contain the following: eggs, milk, peanuts, fish, shellfish, soybeans, wheat, or tree nuts (almond, Brazil nut, cashew, hazelnut, filbert, pine nuts, pistachio, pecan, macadamia and walnut).

### **VOC's**

The Calumet Penreco products listed above contain no Volatile Organic Compounds (VOC) as defined in EPA regulation 40 CFR Part 59, National Volatile Organic Emission Standards for Consumer and Commercial Products. They are also non-VOC as defined by the California Air Resources Board (CARB). These products have vapor pressures less than 0.1 mm Hg at 20 C and they contain predominantly more than 12 carbon atoms per molecule.

### **Kosher Approval**

Calumet Penreco's Karns City and Dickinson facilities are Kosher Certified and Kosher for Passover. Please see our webpage or contact us for a copy of our current Kosher approval letters.

I certify that the statements above are true and correct to the best of my knowledge. If you need a signed copy of this letter with the current date please contact me using the numbers below.

Sincerely,

Christopher L. Miano  
Product Support Manager  
Calumet Specialty Products Partners, L.P.  
chris.miano@calumetspecialty.com