



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

January 1, 2012

Dear Customer,

I am writing to you regarding the following Calumet Penreco products:

Mineral Oils USP and NF (Drakeols®)  
Technical Mineral Oils (Parols®)  
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 21CFR 211 and they are registered with the FDA as Drug Establishments. Copies of FDA Form 2656 are available on request.

**ISO 9001:2000**

Both Calumet Penreco plants have current Certificates of Compliance from ABS Quality Evaluations, Inc. of Houston, TX. Copies of the Certificates are available on request and also in the Certifications area of 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 CA's. 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.

**Cosmetic Applications:**

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



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### **Food Applications:**

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

Calumet Penreco USP petrolatums (including ointment basis) 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 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 21CFR 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.

### **NSF:**

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

### **BSE 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, or Caprine derived diseases being transmitted by the use of these materials.

### **Allergens Statement:**

The 7-th Amendment of the European Cosmetics Directive lists 26-allergens that may be found in cosmetics. None of the Calumet Penreco products shown above contain any of the 26 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, walnut).



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## **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 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,

A handwritten signature in black ink that reads "Harold R. Faust". The signature is written in a cursive style with a prominent initial "H".

Harold R. Faust  
Technical Services  
Calumet Specialty Products Partners, L.P.