

01 January 2024

To Our Valued Customers,

This general regulatory letter is regarding the following Calumet Refining products:

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

FDA Registration

Calumet Refining, LLC 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 9001:2015

Both Calumet Refining 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 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 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.

Cosmetic Applications

Calumet Refining 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 our oils is "Mineral Oil". The INCI name for all our petrolatums is "Petrolatum".

Food Applications

Calumet Refining 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, glutes, fatty acids, pesticide residues, or microbial-based materials. These products also contain no genetically modified organisms (GMO's).

Calumet Refining 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 Refining 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 the Calumet Refining, LLC oils listed above meet FDA regulation 21 CFR 573.680 for use in animal feed.

Calumet Refining USP-NF grade mineral oils, technical grade oil, and USP petrolatums meet numerous other CFR regulations involving indirect food contact. Please contact us at technical@clmt.com regarding your specific application.

Calumet Refining 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 Refining 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.

BSE/TSE Statement

The Calumet Refining, LLC 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 using these materials.

Allergens Statement

The 7th Amendment of the European Cosmetics Regulation lists allergens that may be found in cosmetics. None of the Calumet Refining, LLC 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, tree nuts (almond, Brazil nut, cashew, hazelnut, filbert, pine nuts, pistachio, pecan, macadamia, and walnut) or sesame.



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VOC's

The Calumet Refining 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 Refining's Karns City and Dickinson facilities are Kosher Certified and Kosher for Passover. Please see our webpage or contact us at technical@clmt.com for a copy of our current Kosher approval letters.

Halal Calumet Refining's Karns City and Dickinson facilities have products which are Halal certified. Please see our webpage or contact us at technical@clmt.com 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. Please contact Calumet's Product Support Team at technical@clmt.com should you have further questions.

Sincerely,

Lynn Massad
Technical Market Development Manager