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01 January 2026

Dear Valued Customer,

Calumet Refining, LLC's USP/NF Mineral Oils, White Petrolatum USP, and Petrolatum USP fully comply with the requirements of General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests in the current edition of the United States Pharmacopeia/National Formulary (USP/NF).

Our USP/NF products are anhydrous hydrocarbons derived solely from petroleum feedstocks. These feedstocks undergo severe processing conditions, including hydrotreating at 3,000 psi and 550°F for a minimum of 30 minutes, which eliminates any possibility of microbiological growth. Therefore:

- Calumet does not test every batch for microbiological growth.
- Microbiological data is not reported on Certificates of Analysis.

Annual Testing:

Testing conforming to USP/NF Chapter <61> is performed annually by an independent laboratory on representative mineral oils and petrolatum. Results consistently demonstrate compliance with USP/NF standards. Due to the similar nature of these products, we expect comparable results across all USP/NF grades.

Customer Concerns and Policy:

Calumet understands that customers may have concerns about batch-specific microbiological testing. If a discrepancy arises, the following procedure applies:

- A two-pound sample of the product in question will be sent to Calumet for evaluation.
- Calumet will engage an outside laboratory to test both the customer sample and Calumet's retain sample per USP/NF Chapter <61>.
- If both samples pass, Calumet will not accept the return of the batch.
- If either sample fails, Calumet will accept the return and work with the customer to determine root cause.

Note: This policy applies to **direct customers only**. Indirect customers must address concerns with their supplier.

For further questions regarding microbiological testing, please contact our Technical Product Support Team at technical@clmt.com.

Sincerely,

Lynn Massad
Technical Market Development Manager