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Control of Microbiological Contaminants in Mineral Oil and Petrolatum

To Whom It May Concern:

Mineral oil and petrolatum are completely hydrocarbon systems and do not support microbial growth. Therefore, Calumet Refining, LLC does not maintain a routine microbiological testing program, although we occasionally utilize outside laboratories when necessary.

Potential for Microbial Growth:

Microorganisms can develop at a water-oil interface given sufficient time. To prevent this, Calumet takes extensive measures to exclude water from finished products during storage and shipment.

- Specification: Maximum water content = 50 ppm
- Typical results: Finished products consistently test below 20 ppm

Processing Conditions:

Several production steps inherently destroy microorganisms:

- Hydrotreating: >600°F (315°C) at high hydrogen pressure
- Sulfuric Acid Treatment: Some mineral oils undergo fuming sulfuric acid contact, which destroys proteins and nucleic acids

Storage Tanks:

- Closed tanks with desiccant-equipped vents allow only dry air to enter during drawdown.

Shipping Containers:

- Bulk shipments: Stainless steel tank trucks cleaned with sodium/potassium hydroxide solution, flushed with hot water, and dried with ambient air.
- Inspection: Tanks inspected inside and out; valves dismantled, cleaned, and wrapped.
- Moisture control: ~25 gallons of mineral oil flushed through outlet valves before sealing. (*Petrolatum cannot be flushed due to risk of plugging.*)

Drums and Pails:

- Manufactured to Calumet specifications; cured at >250°F (122°C) for at least 15 minutes.

Filtration:

- 5-micron bag filters used prior to loading into trucks, railcars, drums, and pails. (*Not small enough to remove microorganisms but effective for particulates.*)

Conclusions:

Calumet's approach focuses on preventing water contamination and maintaining a clean environment.

- No disinfectants or sterilization agents are used, eliminating risk of residual chemicals in finished products.
- USP/NF grade mineral oil and petrolatum are routinely tested per USP/NF <61> Microbial Limit Tests and consistently meet acceptable parameters.
- Products are shipped in commercial transports, not sterile environments; customers should take precautions to minimize contamination risk.

For further questions, please contact Calumet's Product Support Team at technical@clmt.com.



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Sincerely,

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